

Gavi Full Country Evaluation

2014 Annual Dissemination Report



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Evaluation Team

This report presents findings from the 2014 Gavi Full Country Evaluations (FCE). It was prepared by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington (UW) in collaboration with members of the FCE Team: International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b); University of Eduardo Mondlane (UEM), Mozambique; Health Alliance International (HAI), Mozambique; the Infectious Diseases Research Collaboration (IDRC), Uganda; the University of Zambia (UNZA), Zambia; and Program for Appropriate Technology in Health (PATH), United States.

This work is intended to inform evidence-based improvements for immunization delivery in FCE countries, and more broadly, in low-income countries, with a focus on Gavi funding. The contents of this publication may not be reproduced in whole or in part without permission from the Gavi Full Country Evaluation Team.

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Acronyms

Acronym	Full term
AAR	After action review
ABCE	Access, Bottlenecks, Costs, and Equity project
AEFI	Adverse event following immunization
ACADEMIC	A Comprehensive Assessment of Diarrhoea and Enteric Disease Management in Children
AIS	AIDS Indicator Survey
AMC	Advance market commitment
APR	Annual Progress Report
BBS	Bangladesh Bureau of Statistics
BCC	Behavior change communication
BCG	Bacillus Calmette-Guérin vaccine
CDC	US Centers for Disease Control and Prevention
CES	Coverage Evaluation Survey
CHAZ	Churches Health Association of Zambia
CHERG	Child Health Epidemiology Reference Group
CHTWG	Child Health Unit Technical Working Group (Zambia)
CHU	Child Health Unit
CIDRZ	Centre for Infectious Disease Research in Zambia
CISM	Manhiça Health Research Centre, Mozambique
cMYP	Comprehensive Multi-Year Plan
CRO	Country Responsible Officer (Gavi)
CRS	Catholic Relief Services
CSO	Central Statistical Office
DAH	Development assistance for health
DBS	Dried blood spot
DFID	United Kingdom Department for International Development
DHO	District Health Officer
DHS	Demographic and Health Survey
DIMO	District Immunization Medical Officer (Bangladesh)
DMO	District Medical Officer
DoV	Decade of Vaccines
DPI	Department of Planning and Information (Zambia)
DPT	Diphtheria-pertussis-tetanus vaccine
DSS	Demographic surveillance site
EAC	External Advisory Committee
ECNEC	Executive Committee of National Economic Council, Bangladesh
EEA	EPI Expenditure Accounts
ELISA	Enzyme-linked immunoassay
EOI	Expression of Intent

EPI	Expanded Program on Immunization
EPITWG	EPI Technical Working Group
ERC	Ethical Review Committee (Bangladesh)
EVMA	Effective Vaccine Management Assessment
FCE	Full Country Evaluations
FCI	Fact-checking interview
FDC	Foundation for Community Development, Mozambique
FGD	Focus group discussion
FMA	Financial Management Assessment
FWA	Family Welfare Assistant
FY	Fiscal year
GBD	Global Burden Of Disease
GDP	Gross domestic product
GHME	Global Health Metrics and Evaluation Conference
GOB	Government of Bangladesh
GOM	Government of Mozambique
GOU	Government of Uganda
GOZ	Government of Zambia
GPR	Gaussian process regression
GHE-S	Government health expenditure as source
GSK	GlaxoSmithKline
HA	Health Assistant
HAI	Health Alliance International
HB	Anti-hepatitis surface antigen
HBc	Anti-hepatitis B core antigen
HBsAg	Hepatitis B surface antigen
HFS	Health Facility Survey
HH	Households
HHS	Household survey
Hib	<i>Haemophilus influenzae</i> type B
HLO	Household listing operation
HMIS	Health Management Information System
HNP	Health Nutrition and Population
HPV	Human papillomavirus
HRH	Human resources for health
HRR	Household response rate
HSS	Health Systems Strengthening
ICC	Interagency Coordinating Committee
icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh
IDRC	Infectious Diseases Research Collaboration
IEC	Information, education, and communication

IFMS	Integrated Financial Management System
IHME	Institute for Health Metrics and Evaluation
IMASIDA	National Survey on HIV/AIDS and Malaria Indicators (Inquérito Nacional de Indicadores de Malária e HIV/SIDA)
INE	National Institute of Statistics, Mozambique
INS	National Institute of Health, Mozambique
IPD	Invasive pneumococcal disease
IPV	Inactivated polio vaccine
IRB	Institutional review board
IRC	Independent Review Committee
ISO	International Organization for Standardization
ISS	Immunization Services Support
IU	International units
JICA	Japan International Cooperation Agency
JSI	John Snow Inc.
KAP	Knowledge, Attitudes, and Practice
KII	Key informant interview
LCMS	Living Conditions Monitoring Survey
LIST	Lives Saved Tool
LR	Linear regression
M&E	Monitoring and evaluation
MCDMCH	Ministry of Community Development, Mother and Child Health
MCH	Maternal and child health
MCHIP	Maternal and Child Health Integrated Programme (Uganda)
MCPA	Malaria Control Policy Assessment project
MIS	Malaria Indicator Survey
MMR	Measles, mumps, and rubella vaccine
MNC&AH	Maternal, Neonatal, Child and Adolescent Health
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare (Bangladesh)
MOU	Memorandum of Understanding
MPM	Multi-partner meeting
MR	Measles-rubella vaccine
MSD	Measles second dose
NCC	National Coordinating Committee (Uganda)
NCIP	Scientific and Technical Sub-Committee of National Committee for Immunization Practice
NGO	Non-governmental organization
NHA	National Health Accounts
NIP	National Immunization Programme (Mozambique)
NMS	National Medical Stores
NP	Nasopharyngeal

NSDS	National Service Delivery Survey
NVS	New Vaccine Support
OD	Optical density
OECD	Organization for Economic Cooperation and Development
OP	Operational plan
OOR	Out-of-range
OPV	Oral polio vaccine
PAED	Programme for Awareness and Elimination of Diarrhoea
PATH	Program for Appropriate Technology in Health
PBF	Post-Bachelor Fellow
PCV	Pneumococcal conjugate vaccine
PETS	Public Expenditure Tracking Survey
PHFI	Public Health Foundation of India
PI	Principal investigator
PIC	Project Implementation Committee
PIE	Post-Introduction Evaluation
PIP	Program implementation plan
PPDPA	Public Procurement and Disposal of Public Assets
PSU	Primary sampling unit
QC	Quality control
QSS	Quality, safety, standards
RCA	Root cause analysis
RFP	Request for Proposals
RRC	Research Review Committee (Bangladesh)
RT	Resource tracking
SAVVY	Sample vital registration with verbal autopsy (Zambia)
SCM	Senior Country Manager
SD	Standard deviation
SHA	System of Health Accounts
SIA	Supplemental immunization activities
SMS	Short message service
SNA	Stakeholder network analysis
SOW	Scopes of work
SVRS	Sample vital registration system
SWAp	Sector-Wide Approach
TA	Technical assistance
TOC	Theory of change
TOT	Training of trainers
TT	Tetanus toxoid
TWG	Technical Working Group
UBOS	Uganda Bureau of Statistics

UEM	University of Eduardo Mondlane
UNCST	Uganda National Council of Science and Technology
UNEPI	Uganda National Expanded Program on Immunization
UNICEF	United Nations Children's Fund
UNPS	Uganda National Panel Survey
UNZA	University of Zambia
USAID	United States Agency for International Development
UW	University of Washington
UW Lab Med	University of Washington, Department of Laboratory Medicine Biomarker Laboratory
VA	Verbal autopsy
VIG	Vaccine Introduction Grant
WHO	World Health Organization
XRP	Radiologically (x-ray) Confirmed Pneumonia
ZISSP	Zambia Integrated Services Strengthening Programme

Executive Summary

Introduction

The Gavi Full Country Evaluations (FCE) project is a prospective study covering the period 2013-2016 with the aim to understand and quantify the barriers to and drivers of immunization program improvement, with emphasis on the contribution of Gavi, the Vaccine Alliance in four countries: Bangladesh, Mozambique, Uganda, and Zambia. The evaluation is carried out by a consortium of institutional partners led by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington (UW), in partnership with the Program for Appropriate Technology in Health (PATH) in the United States; International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) in Bangladesh; University of Eduardo Mondlane (UEM), Health Alliance International (HAI), and Manhica Health Research Centre, Mozambique (CISM) in Mozambique; Infectious Disease Research Collaboration (IDRC) in Uganda; and the University of Zambia (UNZA) in Zambia. The first annual dissemination report, [available online here](#), covered the findings of a process evaluation of the introduction of pneumococcal vaccine (PCV) in Mozambique, Uganda, and Zambia. This second annual dissemination report describes the key findings and recommendations for the 2014 evaluation period across multiple Gavi support streams in all four countries.

Methods

We use a mixed-method approach, covering the full results framework from inputs to impact. The evaluation covers all phases of Gavi support, from the decisions to apply, application and approval, preparation, and implementation and each of the relevant streams of support in the Gavi FCE countries. These include the national introduction of rotavirus vaccine in Zambia, the measles-rubella (MR) campaign in Bangladesh, human papillomavirus (HPV) vaccine (demonstration project in Mozambique, preparations for national introduction in Uganda), as well as early findings on the application process for inactivated polio vaccine (IPV) in all four countries. We follow up on the ongoing implementation of pneumococcal conjugate vaccine (PCV) in Mozambique, Uganda, and Zambia. In addition, we cover cash-based support through the Health Systems Strengthening (HSS) support window in all four countries.

Evaluation components include: a process evaluation using qualitative methods including document review, direct observation, and key informant interviews (KIIs); analysis of secondary data to generate estimates of vaccine coverage and child mortality at subnational levels; analysis of Health Management Information Systems (HMIS) to understand the roll-out of new vaccine introductions; and estimates of national-level expenditure data on immunization. In Zambia, we have implemented a health facility survey of a sample of representative facilities during this this evaluation period; this has included continuous measurement of cold-chain temperatures. In Bangladesh, we implemented pre-and-post-campaign surveys, which included campaign session observation, exit interviews, and health worker surveys. Strengths and limitations of the Gavi FCE are summarized in Table 1.

Table 1: Strengths and limitations of the Gavi FCE

Strengths	Limitations
<ul style="list-style-type: none"> • Mixed-method approach allows for triangulation of findings across evaluation components to increase robustness of findings and provide more in-depth understanding. Findings from one data source also inform the design and implementation of other data collection. • Concurrent evaluation of all relevant streams of Gavi support in a country allows for understanding of the interactions between streams of support. • Whereas other evaluations such as Post Introduction Evaluations (PIEs), monitoring and evaluation of HPV vaccine demonstration projects, or HSS monitoring and evaluation focus on the implementation phase, the Gavi FCE complements these by examining the full process from decision-making to application, preparation, implementation and routinization, and allows identification and linkage of issues earlier in the process with downstream consequences. • Data collection designed to leverage or complement other surveys and activities, such as the Inquérito Nacional de Indicadores de Malária e HIV/SIDA (IMASIDA) in Mozambique (for further mapping and comparison of complementary related activities with the FCE, refer to the 2014 Annual Progress Report [APR]). • Prospective approach allows for collection of information in real-time so that key issues may be identified as they arise and allows for the opportunity to inform implementation process and allow corrective action. 	<ul style="list-style-type: none"> • For this report, not all FCE evaluation components have yet been implemented. • Due to the extent of the scope of the Gavi FCE, there is a limited ability to examine all issues in detail. However, the broad scope compels selective and more in-depth evaluation of critical issues that are priority areas of Gavi and for countries. • Limited ability to prospectively collect information on larger scale political-economic and social processes (e.g., priority setting at the donor level; social displacement and migration at the country level), which affect immunization activities but fall outside the analytical scope of the process tracking of defined milestones. • Limited ability to access informal channels of communication and decision-making, which then limits complete understanding of process. • Absence of a prospective observation mechanism at the regional or global level, and at subnational levels. • Qualitative data collection relies heavily on KIIs that are prone to recall and respondent bias. In each country there are a limited number of stakeholders involved across multiple streams, introducing significant potential for respondent fatigue in key informant interviews. • The timing of surveys means that the evaluation is only able to capture relevant aspects of some, but not all, Gavi support streams. • Secondary data analyses are subject to the availability and quality of the underlying data source (e.g., HMIS, surveys).

Key findings

We identified a number of key findings through our mixed-method approach. We cover the main cross-country findings first, followed by findings specific to each countries' relevant support streams.

Cross-country finding 1: Gavi's Strategic Goal One (the vaccine goal) is "to accelerate the uptake and use of underused and new vaccines by strengthening country decision-making and introduction." In line with this, support from Gavi over the last two years has contributed to the national introduction of PCV in Mozambique, Uganda, and Zambia; rotavirus vaccine in Zambia; and an MR campaign in Bangladesh. Gavi is also supporting an ongoing HPV vaccine demonstration project in Mozambique. In general, PCV and rotavirus vaccine are being delivered at coverage levels comparable to vaccines already in the system. The MR campaign in Bangladesh reached high coverage and reduced rubella disease susceptibility among the target population, as confirmed by a post-campaign survey. Despite this, wider delivery and monitoring and evaluation of new and routine vaccines are constrained by persistent limitations of immunization delivery systems.

Cross-country finding 2: There is a lack of clarity for the primary objective and way to implement HPV vaccine demonstration projects as a mechanism for learning and guiding national HPV vaccine introduction. This is partly driven by insufficient and underutilized technical guidance for countries implementing HPV vaccine demonstration projects. Relatedly, potential pathways from the demonstration project to national introduction are not well articulated. Part of the confusion about the objectives of the demonstration project may stem from a degree of misalignment between the learning objective of the demonstration project and the requirement for countries to have a demonstrated ability to reach 50% of the target cohort in order to qualify for support for national introduction. In other words, in order to meet the requirement of demonstrated ability to deliver HPV vaccine, the demonstration project may not be designed in a way that maximizes the potential learning opportunities for national introduction.

Cross-country finding 3: Gavi's second strategic goal to "contribute to strengthening the capacity of integrated health systems to deliver immunization" is implemented through its HSS support. All Gavi FCE countries have experienced multiple barriers and slow implementation of HSS support, several of which have been previously documented. Barriers range from difficulties in coordinating across multiple stakeholders and other health system strengthening activities, the complex and diverse range of activities, to implementation delays due to bureaucratic systems for fund disbursement and procurement. This slow progress has direct implications on efforts to increase vaccine coverage and reduce inequalities and additionally affects new vaccine introductions.

Cross-country finding 4: Although there is evidence of learning from past experience, planning and management of Gavi support remains an important bottleneck in Mozambique, Uganda, and Zambia. This is a reflection of limited central capacity at the country-level and is exacerbated by concurrent application and implementation of multiple Gavi support streams. We noted several different forms of capacity challenges. These included staff turnover, low numbers of central level staff who are spread too thin, and limited capacity in terms of experience and familiarity with Gavi processes and systems.

Cross-country finding 5: Although there is evidence to suggest that country-level partnerships consisting of Expanded Program on Immunization (EPI) programs, World Health Organization (WHO), UN Children's Fund (UNICEF), and others are growing stronger and expanding to include a greater range of stakeholders, the observed partnerships do not always have the right people, in the right numbers, in the right structures, and with the right motivation to deal with the workload required to apply, plan for, and implement multiple Gavi support streams. Our findings suggest that the Gavi Secretariat, in particular, Senior Country Managers (SCMs), are not necessarily viewed as part of the partnership. A re-

examination of SCM engagement with country stakeholders, including consideration of greater in-country presence may improve the partnership structure, and thus outcomes.

Cross-country finding 6: Communication between the Gavi Secretariat, country partners, and government, particularly around Gavi Secretariat procedures and guidelines, remains an ongoing barrier to progress. There is a need for a set of more formalized procedures and guidelines and increased communication around, for example, changes in plans and roles from the approved application, and around fund disbursement.

In addition to the cross-country findings, we also summarize below the specific key findings identified during this evaluation by country and support stream. For each finding, we designated a ranking that reflects the robustness of evidence for each finding with the four point ranking scale described below.

The robustness ranking does not systematically distinguish between qualitative and quantitative findings. Rather, each finding is assessed in terms of all relevant and appropriate data sources that inform the conclusion, whether the sources be exclusively qualitative or quantitative in nature, or a combination of both.

Ranking	Reason (generic)
A	The finding is supported by multiple data sources (good triangulation) which are generally of good quality. Where fewer data sources exist, the supporting evidence is more factual than subjective.
B	The finding is supported by multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation) of good quality but perhaps more perception-based than factual.
C	The finding is supported by few data sources (limited triangulation) and is perception-based, or generally based on data that are viewed as being of lesser quality.
D	The finding is supported by very limited evidence (single source) or by incomplete or unreliable evidence. In the context of this prospective evaluation, findings with this ranking may be preliminary or emerging, with active and ongoing data collection to follow-up.

Bangladesh

MR campaign finding 1: Bangladesh achieved high awareness of the MR campaign among the population and, subsequently, achieve high coverage of the MR vaccine among the target age group. Differences in coverage were observed, with coverage lower in traditionally lower performing areas, among children with caregivers with no education, and children less than five years of age. High coverage led to large reductions in susceptibility to rubella in the target population. Measles susceptibility was already low prior to the campaign, reflecting historically high sustained routine coverage of measles vaccination and previous measles vaccine campaigns. (*Robustness of finding: A*)

MR campaign finding 2: The MR campaign had a range of positive effects on the routine immunization system, ranging from strengthened delivery systems to increased demand for vaccination. Some negative effects were also noted, including reduced monitoring and supervision of routine EPI due to campaign demands on health worker time. There was also some missed opportunities for catch-up of other vaccines. (*Robustness of finding: A*)

MR campaign finding 3: The MR campaign was not included under the operational plan (OP) of Maternal, Neonatal, Child and Adolescent Health (MNC&AH) as the plan was developed prior to the opening of the Gavi support window for the MR campaign. In the context of Bangladesh, no money can be allocated or spent for any other activities except the line items described in the endorsed OP. The subsequent lengthy administrative procedures required for the release of funds resulted in a delay in approval of the budget for preparatory activities and launch. *(Robustness of finding: C)*

MR campaign finding 4: Some campaign delivery points experienced vaccine stock-outs caused by a number of factors. Suboptimal micro-planning and target population registration led to underestimation of the target population which converged with high vaccine demand, resulting from successful planning activities to result in stock-outs. *(Robustness of finding: A)*

Mozambique

HPV finding 1: The district ultimately chosen as the Gavi-supported site for the HPV vaccine demonstration in Mozambique represents a district with relatively favorable implementation conditions that include strong partner support and comparatively higher socioeconomic conditions. The government of Mozambique's later decision to include and independently fund two additional HPV vaccine demonstration districts will likely lead to lessons learned which will be more applicable and which will result in tools and plans that are better adapted for national introduction. *(Robustness of finding: B)*

HPV finding 2: Insufficient technical guidance and underutilized technical assistance, coupled with the National Immunization Programme (NIP) and country-level partners' limited knowledge on implementing HPV vaccine demonstration projects led to the unsuccessful implementation of a target population census in the HPV vaccine demonstration sites, which was ultimately abandoned. The resources required to conduct the census resulted in a lack of attention being paid to other preparatory activities that affected the quality of the HPV demonstration project. *(Robustness of finding: B)*

HPV finding 3: Funds were disbursed early from Gavi, in response to lessons from Mozambique's experience with PCV. The disbursement entity, roles, and responsibilities of the NIP and partners however, changed, from what was stated in the approved application for the HPV vaccine demonstration project support in Mozambique. Even though these changes were positive because they better aligned with the purpose of the demonstration project, the changes were poorly communicated across all stakeholders and were not well planned. As a result there was confusion in roles and responsibilities and delayed in-country disbursement of funds to implementing agencies. *(Robustness of finding: A)*

HSS finding 1: Communication challenges between the NIP and Gavi Secretariat, coupled with competing priorities and staff turnover at NIP and Gavi, led to submission delays in the development of key Gavi HSS conditionalities (Year 1 OP and Monitoring and Evaluation [M&E] framework) and the start-up of HSS support in Mozambique. *(Robustness of finding: B)*

Uganda

HPV finding 1: Key steps in the application process failed to account for the feasibility, sustainability, and ongoing financial resources required for the chosen and tested HPV vaccine delivery model (a combination of school-based and campaign-based delivery) for national introduction. These failures include lack of participation in the application development process on the part of key partners who could have provided this financial perspective, and failure of the Independent Review Committee (IRC) review process to ensure that this information was provided prior to approval of the application. This led to a switch to a delivery model based on routine EPI that was not one of the primary models tested as part of the HPV vaccine demonstration project in Uganda. *(Robustness of finding: B)*

HPV finding 2: Lessons learned from the introduction of PCV led to the Uganda National Expanded Programme on Immunisation (UNEPI) and partners initiating the preparatory phase for the national HPV vaccine introduction earlier than past vaccine introductions. However, there was uncertainty among in-country stakeholders as to when the Vaccine Introduction Grant (VIG) funds would arrive in country to cover the costs of the preparatory activities. This is the result of a mismatch in the understanding of the procedures and timeline for the disbursement of the HPV vaccine introduction grant between the Gavi Secretariat, UNEPI, and partners. *(Robustness of finding: C)*

HSS/ISS finding 1: Challenges with the integrated financial management system (IFMS), poor communication between national and subnational levels, non-integration of ISS into the district planning cycle, and a lack of guidelines for districts on how to spend and account for ISS funds have led to slow utilization of ISS funds in Uganda. Notably, the Ministry of Health (MOH) has addressed these challenges; they sent advance communication to districts to notify them of future ISS disbursements and provided guidelines detailing how these funds were to be utilized and accounted for. *(Robustness of finding: A)*

HSS/ISS finding 2: Both HSS and ISS implementation were delayed by the protracted time period required for procurement of equipment and civil works through the Uganda government system and the subsequent transition of procurement to non-governmental partners. These delays were exacerbated by the concurrent reprogramming of HSS funds. The country did not anticipate the time that the procurement transition would take and did not fully realize the implications it would have on spending all HSS funds within the specified support window. *(Robustness of finding: C)*

PCV finding 1: As documented in the 2013 Gavi FCE report, despite plans to rapidly roll out PCV nationwide after the initial PCV launch in one district in April 2013, a WHO readiness assessment in September 2013 determined that the MOH was not prepared to introduce PCV. In the wake of this assessment, stronger in-country partnerships emerged between UNEPI, National Medical Stores (NMS), and other non-governmental partners to mentor and reorient health workers, achieve readiness, and distribute vaccines to all districts, ultimately leading to nationwide rollout. *(Robustness of finding: A)*

PCV finding 2: Although the majority of districts received PCV within one month after WHO declared the country ready, a number of districts experienced continued postponements in the introduction of PCV due to delayed training of health workers resulting from delayed access to funds at the district level. The underlying causes of the delays were staff turnover that led to new district staff submitting incorrect account numbers to the national level, the multi-step process of transferring funds from the national to district level through IFMS, and poor communication at various levels. *(Robustness of finding: A)*

Zambia

PCV/Rotavirus finding 1: Discrepancies between vaccine consumption and official target population figures that are used to determine vaccine supply, remaining cold-chain inadequacies at facilities, and lack of adequate planning and vaccine stock management at the subnational level contributed to stock-outs of both PCV and rotavirus vaccines. (*Robustness of finding: A*)

PCV/Rotavirus Finding 2: Ongoing limitations of the vaccine surveillance system, including lack of tools and forms at facility levels, inaccurate denominators, insufficient health worker training, and incomplete reporting limit the ability of the EPI program to track the roll out of PCV and rotavirus vaccine in terms of vaccine coverage, adverse events, and other indicators. (*Robustness of finding: A*)

Zambia PCV/Rotavirus Finding 3: Experience gained through the pilot implementation of rotavirus vaccine in Lusaka province and adaptations based on informal lessons learned during the launch of PCV in 2013 contributed to improved preparation, launch, and roll out of the rotavirus compared to previous introductions. A formal PIE and a longer time period between the introductions could have potentially allowed for greater learning and opportunity to address past limitations prior to the rotavirus vaccine introduction. (*Robustness of finding: B*)

HSS Finding 1: Coordination challenges stemming from the different partnership structure for HSS compared to new vaccine introductions, limited experience with the new HSS application process, and multiple competing priorities led to a revision of the timeline for the HSS application submission from September 2014 to January 2015. (*Robustness of finding: C*)

Recommendations

Based on the key country-specific findings described above, we developed a series of recommendations that are summarized in Table 2.

Table 2: Recommendations by country and support stream

Finding	Recommendation(s)	Audience	Generalizability
Bangladesh			
<i>Measles-rubella (MR) vaccine</i>			
<p>Bangladesh achieved high awareness of the MR campaign among the population and, subsequently, achieve high coverage of the MR vaccine among the target age group. Differences in coverage were observed, with coverage lower in traditionally lower performing areas, among children with caregivers with no education, and children less than five years of age. High coverage led to large reductions in susceptibility to rubella in the target population. Measles susceptibility was already low prior to the campaign, reflecting historically high sustained routine coverage of measles vaccination and previous measles vaccine campaigns.</p>	<ol style="list-style-type: none"> 1. Following an overall successful MR campaign, the Bangladesh EPI and country-level partners should consider targeted efforts that focus on low coverage areas and groups, as identified by surveillance and coverage data, and shift attention to maintaining high routine MR vaccine coverage. 2. The Bangladesh EPI program and country-level partners should focus future social mobilization and demand generation activities on increasing awareness and understanding of rubella. 	<p>Bangladesh EPI, WHO, and UNICEF</p>	<p>Low. The finding and accompanying are to the MR campaign in Bangladesh.</p>
<p>The MR campaign had a range of positive effects on the routine immunization system, ranging from strengthened delivery systems to increased demand for vaccination. Some negative effects were also noted, including reduced monitoring and supervision of routine EPI due to campaign demands on health worker time. There was also some</p>	<ol style="list-style-type: none"> 1. Gavi and partners should ensure that appropriate technical guidance is provided to EPI programs in the design of campaigns so that positive impacts are maximized and negative impacts are minimized. This includes, but is not limited to, designing campaigns as an opportunity for provision of catch for other vaccines. 	<p>Gavi Secretariat, WHO, and UNICEF</p>	<p>Medium. While the finding is for Bangladesh, ensuring that campaign positive effects are maximized and negative effects are minimized is likely true for other countries undertaking large-scale immunization campaigns. This issue was also highlighted across a number of countries in the March 2015 IRC</p>

Finding	Recommendation(s)	Audience	Generalizability
missed opportunities for catch-up of other vaccines.			report. Clear technical guidance on how countries can achieve this will facilitate this.
The MR campaign was not included under the operational plan (OP) of Maternal, Neonatal, Child and Adolescent Health (MNC&AH) as the plan was developed prior to the opening of the Gavi support window for the MR campaign. In the context of Bangladesh, no money can be allocated or spent for any other activities except the line items described in the endorsed OP. The subsequent lengthy administrative procedures required for the release of funds resulted in a delay in approval of the budget for preparatory activities and launch.	1. Country governments should initiate dialogue internally and with the Gavi Secretariat about country needs and administrative requirements for new support streams well in advance of the opening of the support window to enable timely updating of key operational documents (e.g., Comprehensive Multi-year Plan [cMYP] and).	Country governments and Gavi Secretariat	Low. We propose, however, that this issue is explored more broadly in other settings.
Some campaign delivery points experienced vaccine stock-outs caused by a number of factors. Suboptimal micro-planning and target population registration led to underestimation of the target population which converged with high vaccine demand, resulting from successful planning activities to result in stock-outs.	1. The Ministry of Health and Family Welfare (MOHFW) and country-level partners should draw on MR campaign lessons and continue to invest in maintaining and institutionalizing the strong capacity for contingency management that can be carried forward for future vaccine introductions.	MOHFW, WHO, and UNICEF country offices	Low. This finding is specific to the MR campaign in Bangladesh.

Finding	Recommendation(s)	Audience	Generalizability
	2. The MOHFW and EPI program should explore methods to better incorporate perspectives of stakeholders from various levels of the health system into higher-level decision-making with the goals of strengthening alignment and effectively implementing activities.		
Mozambique			
<i>Human papillomavirus (HPV) vaccine</i>			
The district ultimately chosen as the Gavi-supported site for the HPV vaccine demonstration in Mozambique represents a district with relatively favorable implementation conditions that include strong partner support and comparatively higher socioeconomic conditions. The Government of Mozambique (GOM)'s later decision to include and independently fund two additional HPV vaccine demonstration districts will likely lead to lessons learned which will be more applicable and which will result in tools and plans that are better adapted for national introduction.	1. Gavi and country governments should continue to ensure that selection of demonstration sites maximizes the potential for a representative experience that may contribute to lessons learned for national introduction. This may include supporting multiple demonstration sites in a simultaneous or phased manner and/or encouraging co-financing of additional demonstration sites by country governments or other donors.	Country governments and Gavi Secretariat	Medium. While site selection was a finding specific to Mozambique, our interviews at the global level suggest that this may be occurring in other countries. A review of site selection in other countries is warranted.

Finding	Recommendation(s)	Audience	Generalizability
<p>Insufficient technical guidance and underutilized technical assistance, coupled with the National Immunization Programme (NIP) and country-level partners' limited knowledge on implementing HPV vaccine demonstration projects led to the unsuccessful implementation of a target population census in the HPV vaccine demonstration sites, which was ultimately abandoned. The resources required to conduct the census resulted in a lack of attention being paid to other preparatory activities that affected the quality of the HPV demonstration project</p>	<ol style="list-style-type: none"> 1. The Gavi Secretariat and partners should provide technical guidelines for HPV vaccine demonstration project implementation that includes guidance on how demonstration activities relate to national roll out of the HPV vaccine. Relatedly, in guidelines, the demonstrated ability criterion should be revised to more clearly emphasize demonstrated ability based on an average or representative site and conditional on development of a feasible delivery model for national introduction 2. Partners and Gavi should ensure that sufficient technical guidance (guidelines, tools, and also technical assistance) specific to HPV vaccine demonstration projects is available and accessible. 	Gavi Secretariat, WHO, and UNICEF	High. As the HPV vaccine involves a target population in other countries that is very different from those for routine EPI, there is likely to be limited technical expertise in country to design delivery models to reach the target population on a routine basis. The absence of specific demonstration project guidelines will affect all countries. A review of technical capacity and assistance needs for HPV vaccine demonstration programs is warranted.
<p>Funds were disbursed early from Gavi, in response to lessons from Mozambique's experience with PCV. The disbursement entity, roles, and responsibilities of the NIP and partners however, changed, from what was stated in the approved application for the HPV vaccine demonstration project support in Mozambique. Even though these</p>	<ol style="list-style-type: none"> 1. The Gavi Secretariat should establish a formalized process for changes to implementation plans that occur after approval, including changes in designated roles and funding recipients. Country governments, country-level partners and the Gavi Secretariat should ensure that changes in 	Gavi Secretariat, country partners, and country governments	Medium. Our finding suggests that the process for changing roles and responsibilities from the initial application are not formalized, which may lead to similar issues in other countries.

Finding	Recommendation(s)	Audience	Generalizability
changes were positive because they better aligned with the purpose of the demonstration project, the changes were poorly communicated across all stakeholders and were not well planned. As a result there was confusion in roles and responsibilities and delayed in-country disbursement of funds to implementing agencies.	<p>these roles are communicated to all relevant parties.</p> <p>2. Gavi should continue to ensure that the leading implementer for demonstration is the MOH if they will be the main implementer for national introduction.</p>		
<i>Health system strengthening (HSS)</i>			
Communication challenges between the NIP and Gavi Secretariat, coupled with competing priorities and staff turnover at NIP and Gavi, led to submission delays in the development of key Gavi HSS conditionalities (Year 1 OP and Monitoring and Evaluation [M&E] framework) and the start-up of HSS support in Mozambique.	<p>1. In countries with limited central capacity and/or other important implementation bottlenecks, country governments, partners, and Gavi should more carefully consider whether implementing multiple support streams is feasible. For Mozambique, this extends to a reassessment of the feasibility of current plans to introduce rotavirus vaccine, measles second dose vaccine, and IPV in 2015 alongside the ongoing implementation of the HPV vaccine demonstration project and the expected start-up of HSS.</p> <p>2. Country governments, partners, and Gavi should consider strengthening central capacity and additional technical support to allow countries to manage and implement multiple support</p>	Gavi Secretariat, Alliance partners, and country governments	Medium. Limited central capacity was a challenge in three of the four Gavi FCE countries is likely to be a problem common to many countries. This is particularly the case in the context of the implementation of multiple streams of Gavi support.

Finding	Recommendation(s)	Audience	Generalizability
	<p>streams. This could be implemented through the existing HSS support stream.</p> <p>3. Gavi should improve communication by jointly developing explicit communication norms, roles and expectations of NIP/MOH managers, key Alliance partners (e.g. UNICEF, WHO), and the Gavi Secretariat, through written and mutually agreed upon terms of references. This should include alternate designees to limit the problem of staff turnover.</p>		
Uganda			
<i>Human papillomavirus (HPV) vaccine</i>			
<p>Key steps in the application process failed to account for the feasibility, sustainability, and ongoing financial resources required for the chosen and tested HPV vaccine delivery model (a combination of school-based and campaign-based delivery) for national introduction. These failures include lack of participation in the application development process on the part of key partners who could have provided this financial perspective, and failure of the Independent Review Committee (IRC) review process to ensure that this</p>	<p>1. Acknowledging that HPV vaccine targets a different age group than other routine vaccines, country governments, partners, and Gavi should more comprehensively consider the costs and plan for sustainability of the chosen national delivery strategy. As this is a specific criterion of Gavi’s previous and new application guidelines, it is essential that this be included in the application materials and could be ensured by incorporating a section in the</p>	<p>Country governments and Gavi Secretariat</p>	<p>Medium. Part of this finding stems from the need for a more careful review of financial sustainability by the IRC and Gavi Secretariat, suggesting that this may be occurring in other settings. We suggest follow-up investigation on the issue of financial sustainability of national HPV vaccine introduction in other countries.</p>

Finding	Recommendation(s)	Audience	Generalizability
<p>information was provided prior to approval of the application. This led to a switch to a delivery model based on routine EPI that was not one of the primary models tested as part of the HPV vaccine demonstration project in Uganda.</p>	<p>application template dedicated to the costing and planning for ongoing vaccine delivery. This information should be carefully reviewed by the IRC and Gavi Secretariat.</p> <ol style="list-style-type: none"> <li data-bbox="720 493 1213 699">2. MOHs, partners, and Gavi should increase efforts to integrate the Ministry of Finance into all immunization-related partnerships and the Ministry of Education for HPV-specific partnerships. <li data-bbox="720 740 1213 1162">3. Country governments and partners when designing HPV vaccine demonstration projects should, where feasible, consider including different delivery models that vary in the resources required to implement them. For example, demonstration projects could test whether a lower-cost option of integrating HPV vaccination as part of the routine EPI delivery system is effective. 		

Finding	Recommendation(s)	Audience	Generalizability
<p>Lessons learned from the introduction of PCV led to the Uganda National Expanded Programme on Immunisation (UNEPI) and partners initiating the preparatory phase for the national HPV vaccine introduction earlier than past vaccine introductions. However, there was uncertainty among in-country stakeholders as to when the Vaccine Introduction Grant (VIG) funds would arrive in country to cover the costs of the preparatory activities. This is the result of a mismatch in the understanding of the procedures and timeline for the disbursement of the HPV vaccine introduction grant between the Gavi Secretariat, UNEPI, and partners.</p>	<p>1. The Gavi Secretariat should establish a formal process for requesting vaccine introduction grants which should include details on the timing of disbursement.</p>	<p>Gavi Secretariat</p>	<p>High. This finding is similar to what was reported as part of the 2013 Gavi FCE report and reflects the need for a more formalized process for requesting vaccine introduction grants.</p>
<p><i>Health system strengthening (HSS) and immunization services support (ISS)</i></p>			

Finding	Recommendation(s)	Audience	Generalizability
Challenges with the integrated financial management system (IFMS), poor communication between national and subnational levels, non-integration of ISS into the district planning cycle, and a lack of guidelines for districts on how to spend and account for ISS funds have led to slow utilization of ISS funds in Uganda. Notably, the Ministry of Health (MOH) has addressed these challenges; they sent advance communication to districts to notify them of future ISS disbursements and provided guidelines detailing how these funds were to be utilized and accounted for.	<ol style="list-style-type: none"> 1. The Uganda MOH should ensure adequate and timely communication to subnational levels about Gavi cash support so that funds are integrated into the district planning process. The MOH should ensure that Gavi cash support is disbursed to the subnational level with accompanying guidelines on use and accountability. 2. The application and planning process for HSS (and other new vaccine introductions dependent on HSS funds) should more realistically take into account the 	Uganda MOH	Low. This finding is specific to Uganda.

Finding	Recommendation(s)	Audience	Generalizability
Both HSS and ISS implementation were delayed by the protracted time period required for procurement of equipment and civil works through the Uganda government system and the subsequent transition of procurement to non-governmental partners. These delays were exacerbated by the concurrent reprogramming of HSS funds. The country did not anticipate the time that the procurement transition would take and did not fully realize the implications it would have on spending all HSS funds within the specified support window.	<p>time required for government systems (e.g., Public Procurement and Disposal of Public Assets [PPDPA], IFMS) and the time needed for reprogramming. Gavi should consider the time required for reprogramming when setting specified support windows.</p> <p>3. Country governments, partners, and the Gavi Secretariat should more carefully consider the implications on country alignment and efficiency of deviations from government-based systems of funding and procurement. Decisions to switch to alternate funding channels should further consider the time required to undertake these transitions.</p>	Country governments, WHO, UNICEF, and Gavi Secretariat	High. Although the findings are specific to Uganda, challenges with procurement as part of HSS grants have been noted in other evaluations of HSS.
Zambia			
<i>Pneumococcal vaccine (PCV), measles second-dose (MSD), and rotavirus vaccine</i>			
Discrepancies between vaccine consumption and official target population figures that are used to determine vaccine supply, remaining cold-chain inadequacies at facilities, and lack of adequate planning and vaccine stock management at the subnational level contributed to stock-outs of both PCV and rotavirus vaccines.	1. In Zambia, substantial long-term investment and multi-sectorial involvement are required to develop more accurate estimates of target populations for measuring vaccine coverage and determining vaccine supply. In the nearer term, the EPI program with appropriate stakeholders, including districts,	Zambia EPI, Central Statistical Office (CSO), WHO, and UNICEF	Medium. This finding is specific to Zambia, however, supply chain issues are a problem affecting several Gavi support countries as highlight in the March 2015 IRC report.

Finding	Recommendation(s)	Audience	Generalizability
	<p>CSO and partners such as WHO and UNICEF should identify solutions to mitigate the effect of inaccurate denominators leading to vaccine stock-outs</p> <p>2. There should be continued investment in cold-chain capacity, maintenance and logistics should be a key focus on health system strengthening activities in Zambia.</p>		
<p>Ongoing limitations of the vaccine surveillance system, including lack of tools and forms at facility levels, inaccurate denominators, insufficient health worker training, and incomplete reporting limit the ability of the EPI program to track the roll out of PCV and rotavirus vaccine in terms of vaccine coverage, adverse events, and other indicators.</p>	<p>1. Data quality is a key focus of the latest HSS support stream. Consistent with this focus and the findings of the evaluation, the upcoming application for HSS in Zambia should include substantial investments to address the issue of data quality, including ensuring availability of forms and tools, as well as training to ensure accurate reporting.</p>	<p>Zambia MOH</p>	<p>Medium. Although this finding is specific to Zambia, data quality for immunization programs is an issue known to affect many other countries, as also highlighted in the latest March 2015 IRC report.</p>

Finding	Recommendation(s)	Audience	Generalizability
Experience gained through the pilot implementation of rotavirus vaccine in Lusaka province and adaptations based on informal lessons learned during the launch of PCV in 2013 contributed to improved preparation, launch, and roll out of the rotavirus compared to previous introductions. A formal PIE and a longer time period between the introductions could have potentially allowed for greater learning and opportunity to address past limitations prior to the rotavirus vaccine introduction.	1. EPI programs, country partners and Gavi should ensure that learning experiences are maximized for new vaccine introductions. Learning from previous introductions should be based on robust post-launch monitoring and evaluation, including PIEs. This should also include sufficient time between introductions to allow corrective actions to be taken. Another option is to explore further the use of phased introductions such as through the use of pilot or demonstration projects that provide opportunities for early identification and resolution of bottlenecks and partnership strengthening.	EPI programs, WHO, UNICEF, and Gavi secretariat	Medium. Although this finding is specific to Zambia, we note other instances, for example Mozambique, where multiple vaccine introductions are scheduled close in time. This may limit the ability to undertake PIEs between introductions and the opportunity to address deficiencies from previous introductions.
<i>Health system strengthening (HSS)</i>			
Coordination challenges stemming from the different partnership structure for HSS compared to new vaccine introductions, limited experience with the new HSS application process, and multiple competing priorities led to a revision of the timeline for the HSS application submission from September 2014 to January 2015.	1. Ministry of Community Development, Mother and Child Health (MCDMCH) should identify a dedicated point person within Department of Planning and Information to coordinate the application of the HSS grant in Zambia.	Zambia MCDMCH	Medium. Although the finding is specific to Zambia, challenges with coordination for HSS have been noted in previous evaluations of HSS.

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Chapter 1: Overview of Gavi Full Country Evaluations

Introduction

The Gavi Full Country Evaluations (FCE) project is a prospective study to understand and quantify the barriers to and drivers of immunization program improvement, with emphasis on the contribution of the Gavi, the Vaccine Alliance, in four countries: Bangladesh, Mozambique, Uganda, and Zambia.¹ A number of important principles underlie the Gavi FCE: harmonizing monitoring and evaluation activities in each country by leveraging available data; working collaboratively with partners to conduct targeted primary data collection; strengthening country ownership and capacity, by partnering with in-country institutes and undertaking shared learning activities; and providing timely, regular, and systematic feedback to countries and Gavi, the Vaccine Alliance. A full description of the Gavi FCE can be found in the [first annual progress report](#).

This second annual dissemination report describes key findings and recommendations for the 2014 evaluation period. The report first describes the evaluation components relevant to this report. We then present key findings along with recommendations for each of the four countries, organized by individual Gavi funding streams. In addition, we identify common issues identified across streams of support. Lastly, we identify common cross-country themes that have emerged during the evaluation period, present a summary of the findings by the key evaluation questions, and discuss the strengths and limitations of the FCE findings for this report. As part of the key findings, we also follow up on issues reported on as part of the 2013 report. We provide a summary of recommendations at the end. Detailed methods of the evaluation and additional results are included in annexes.

Evaluation methods

The Gavi FCE is a mixed-method evaluation, covering the full results framework from inputs to impact. Consistent with the prospective approach, the evaluation has focused on Gavi support streams undertaken during the evaluation period. This section briefly describes the methods utilized in generating the findings covered in this report. We do not cover all methods that are utilized in the Gavi FCE; further details on the full suite of evaluation components that the FCE is implementing across the evaluation can be found in the [first annual progress report](#). Further details of each method applied by country are included in each country section and in accompanying annexes.

Theory of Change

For the purposes of this evaluation, the Gavi FCE team retrospectively developed a theory of change (TOC) for each of the relevant Gavi support streams active in the FCE countries. TOC is a method widely used in international development and evaluation research.¹ The TOCs were developed with feedback from the Gavi Secretariat and other stakeholders at the global and country level and are presented in Annex 1.

Each TOC describes key milestones to be achieved and the relationships necessary for successful implementation of the relevant stream of support. The TOCs guide the evaluation by providing a way to

¹ India was originally one of five countries included in the full country evaluations (in addition to Bangladesh, Mozambique, Uganda, and Zambia). Following further discussions and elaboration of work plans since the approval of its Health Systems Strengthening (HSS) grant in late 2013, and to avoid duplication of work, India has decided to take forward the work planned as part of the FCE through its Gavi HSS grant. Further explanation can be found in the Gavi FCE Annual Progress Report for 2014.

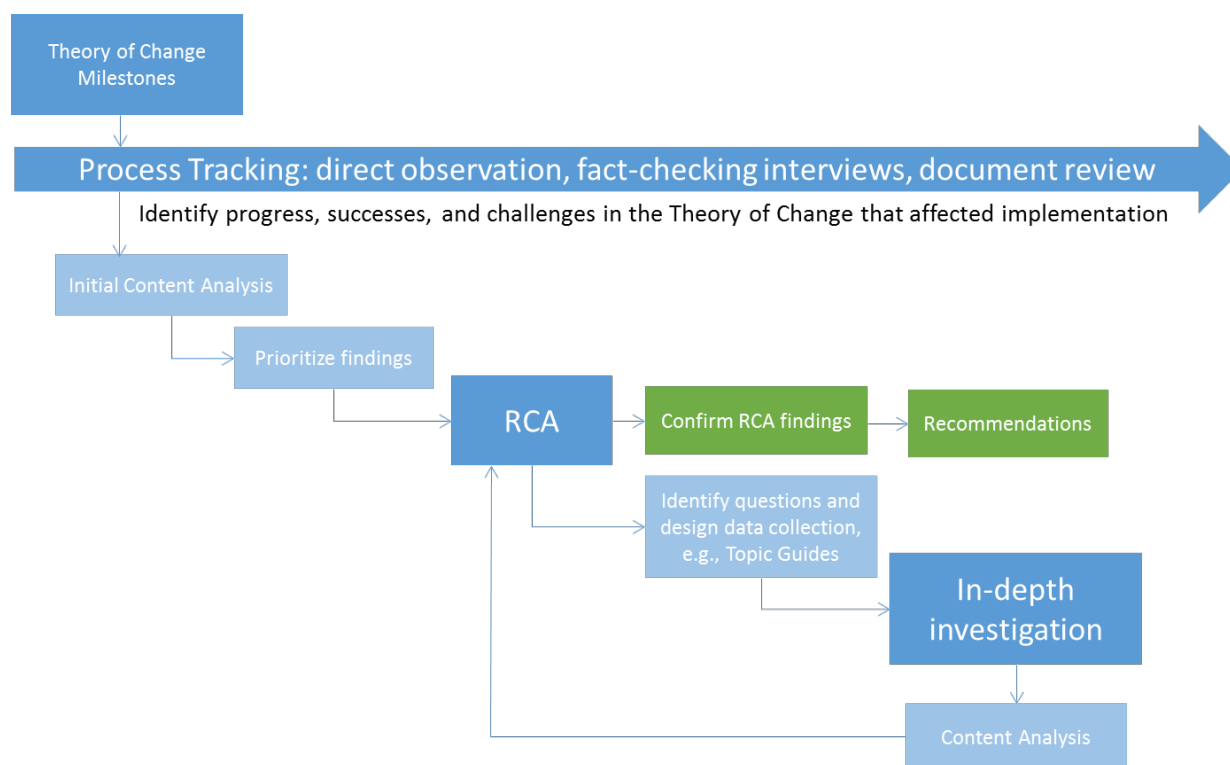
systematically gather data and compare observed processes to what is expected. They provide a framework for systematic analysis of findings from different evaluation components; both quantitative and qualitative indicators are utilized to evaluate the milestones of the TOCs.

Process evaluation

The process evaluation is an important component of the evaluation that examines the interface between Gavi and countries as Gavi inputs (including financial and technical assistance) are applied for, received, and implemented. A process evaluation examines the quality of the process as opposed to the quality of its products, with the underlying assumption that improving the process will improve the outputs and outcomes. The prospective process evaluation employs a developmental approach,² with various stakeholders of the evaluation engaged in the design, collection, synthesis, and use of findings throughout the study. The intent of the FCE process evaluation is to address four overarching questions:

1. To what extent is the process of providing Gavi support to countries improving over time? What has improved, what has not improved, and why?
2. What are intended and unintended consequences of Gavi support across different levels of the immunization system, and why have these consequences occurred?
3. To what extent is the design of Gavi support and its implementation relevant to the country's needs and aligned with the country's priorities and systems?
4. What is the added value of Gavi as a partnership at the country level?

The process evaluation for this report involved three interrelated categories of data collection and analysis, reflecting different levels of depth of investigation carried out over time: 1) process tracking; 2) root cause analysis (RCA); and 3) in-depth investigation. Figure 1 provides a cross-sectional view of how these steps relate to one another.

Figure 1: Cross-sectional view of process evaluation

Process tracking

Process tracking monitors the implementation and timing of planned and unplanned activities, facilitates identification of key stakeholders and decision-making processes, and documents outputs.³ Process tracking simultaneously covers multiple streams of support in the FCE countries and is carried out in sustained manner throughout the evaluation. Generally, process tracking assesses four elements of the process, which are reflected in the indicators that guide the assessment of each milestone in the TOC:

1. **Comprehensiveness:** to what extent have the activities necessary for successful implementation been included in work plans? Or conversely, to what extent are unplanned activities conducted in order to complete tasks?
2. **Completeness:** to what extent are planned activities completed?
3. **Timeliness:** to what extent are activities started, sequenced, and completed in a timely manner?
4. **Partnership/relationships:** for each task, which stakeholders are involved and what roles do they play? How do they interact around achieving programmatic goals?

Process tracking used three data collection methods: 1) direct observation of meetings and events; and 2) review of programmatic documents and other secondary data sources, and fact-checking interviews (FCI). FCIs are informal, opportunistic interactions with stakeholders to verify process tracking information; in this way they are distinguished from the more formal KIIs described below. In addition to addressing the above questions, process tracking served to identify areas for in-depth qualitative and quantitative analysis.

For managing findings and conducting initial content analysis, the evaluation team documented all noted progress, successes, and challenges in milestone tables for each priority funding stream, ensuring that each finding was aligned with the appropriate TOC milestone. Corresponding data sources were also documented. These tables were refined in step with ongoing process tracking.

For deeper qualitative content analysis of observation notes, documents, and FCIs the FCE Team developed a structured coding framework based on the TOC milestones and associated indicators as listed above from each funding stream. Evaluation teams in country developed free-codes based on themes and patterns emerging from country-data. Various computer-based tools were used for document management, coding, data reduction, and synthesis including Microsoft Word and Excel as well as dedicated qualitative data analysis software (NVivo and Atlas Ti). Key themes and patterns identified in these aspects of qualitative analysis were then used as inputs for RCA.

Root cause analysis (RCA)

RCA is a procedure for identifying underlying causes of identified challenges and successes. A “root cause” is a key factor in a causal chain of events that, if removed from the sequence, would prevent the final undesirable or desirable event from occurring or recurring.^{4,5} In 2014, we employed a more systematic approach to RCA across all countries, using it to prioritize process tracking findings along with selected survey findings, and then to construct diagrams of causal chains to visually illustrate the dynamic links between observed challenges or successes to possible root causes. This process was iterative because RCA diagrams were continually refined through testing assumptions against multiple data sources and through collective deliberation. In this way, RCA enabled both intermediate-stage development of hypotheses and key questions for in-depth investigation as well as end-stage confirmation of assumptions and development of recommendations.

In-depth investigation

In-depth methods in process evaluation included KIIs, focus group discussion (FGD), and AAR (after-action review). In general, these were the principle means for qualitatively investigating key questions that emerge from process tracking and RCA. Research questions at this level are not pre-specified by the evaluation team, but rather leverage the prospective nature of the evaluation design to focus on prioritized areas for clarification. In 2014, only KIIs were employed for qualitative in-depth investigations using standard techniques from social science and evaluation research.^{6,7,8} This involved designing topic guides based on RCA and engaging with key stakeholders (in-person or virtually) to address questions from the topic guides.

Additionally, this year we implemented a more structured and in-depth approach to address the question of the “added value” of the Gavi partnership. This approach considered various aspects of partnership, including country context, partnership structure, partnership practices and partnership performance^{9,10}. A detailed description of these constructs and associated indicators in the analytic framework is provided in Annex 11. The partnership analysis involved targeted key informant interviews and a partnership survey for stakeholder network analysis (SNA). Dedicated interviews on partnership as well as the survey and SNA were used only in Uganda this year, however partnership-related questions were included in KII topic guides in all countries whenever appropriate. The partnership approach will be expanded to other countries in 2015 as relevant for addressing questions and testing assumptions that emerge from root cause analysis.

Qualitative content analysis of KIIs followed similar procedures described above in process tracking. SNA was carried out with MS Excel and UCINET software.

Resource tracking

Components of the resource tracking (RT) studies were completed in Mozambique and Uganda for this report. Resource tracking studies are also presently underway in Bangladesh and Zambia. The focus of the RT component in these countries is to shed light on the flow and use of resources (financial, commodities, and technical assistance) for immunization programs. The RT work this year investigated two main questions:

- What Gavi support (by type of support) is allocated on immunization and other related activities, such as health system development?
- What is the contribution of other external donors' allocations on immunization and other related activities?

This was implemented using the System of Health Accounts (SHA) framework methodology. Annex 8 and Annex 10 provide further details on the methods and results for this component.

Health Facility Survey

The Health Facility Survey (HFS) was completed in Zambia in November 2014 and contributed preliminary findings to this report. As described in our previous reports, we utilize a standardized methodology based on the facility surveys from the Access, Bottlenecks, Costs, and Equity (ABCE) project. The HFS in Uganda is presently underway. Surveys in Bangladesh and Mozambique will be implemented in 2015 and findings from these will be included in future reports. Detailed methods for this survey are available in Annex 12. In order to measure the strength of immunization systems, as well as how Gavi support has contributed to addressing system bottlenecks, we collected a range of data on a sample of health facilities in Zambia as shown in Table 3.

Table 3: Health Facility Survey components and indicators

Survey component	Specific indicators
Facility inputs and finances	<ul style="list-style-type: none"> - Geo-location of the facility - Selected non-medical equipment available and functional - Expenditure for previous four fiscal years, total and by categories - Revenues for previous four fiscal years, total and by source - User fees

Survey component	Specific indicators
Facility and staff characteristics	<ul style="list-style-type: none"> - Staff counts by category - Pneumococcal conjugate vaccine (PCV) and rotavirus vaccine training - Performance-based financing - Immunization meetings, including following adverse events - Vaccine monitoring tools, official and improvised - Immunization guidelines - First date of availability of PCV and rotavirus vaccines - Frequency of district supervision at the facility - Hours of operation - Availability of electricity - Frequency of power outages
Vaccine supply, delivery, and cold-chain capacity	<ul style="list-style-type: none"> - Vaccine order system, delivery, and pickup - Frequency and delays of shipments and pickups - Bundling of supplies - Vaccine and vaccine supply shortage procedures - Vaccine availability and stock-outs - Inventory of vaccine storage equipment, including whether equipment currently functional, broken, or without power - Presence of PCV stickers, thermometers - Extraction of manual temperature monitoring chart - Inventory of generators and gas cylinders for backup power - Vaccine handling procedures
Delivery form and Health Management Information System (HMIS) data extraction	<ul style="list-style-type: none"> - Extraction from vaccine order and delivery forms for previous 18 months - Extraction from vaccine supply order and delivery forms for previous 18 months - Vaccine doses administered for previous four years - General facility outputs (births, outpatient visits, inpatient bed-days) - Human resources, including human resources specific for vaccination - Availability of essential medicines and supplies - Immunization outreach and home visits
Direct and assisted observation of facility areas and immunization session	<ul style="list-style-type: none"> - Vaccine posters in patient areas - Facility cleanliness and structure - Sharps supply waste disposal area - Vaccine disposal - Syringe safe storage - Vaccine carrier stored in the shade - Temperature of carriers - Number of ice packs in the carrier and their state

In addition to collecting information at the facility level, the project also collects key information from District Health Offices (or their equivalent) including expenses, human resources, and infrastructure. The facility survey also includes a patient exit interview component, collecting information from those who

recently got a child vaccinated or attempted to get a child vaccinated on user fees, patient perceptions of quality, and patients' health care experience.

Continuous temperature monitors

An innovative method employed by the Gavi FCE in the HFS is the use of continuous temperature monitors. In Zambia, 116 continuous temperature loggers were used to capture the refrigerator temperature over an extended time period. These devices capture temperatures in one-minute intervals, ranging from -40°C to 80°C (-40°F to 176°F) at a resolution of 0.1°C (0.3°F). It is accurate to $\pm 0.5^\circ\text{C}$ ($\pm 0.9^\circ\text{F}$). Detailed results from the temperature monitor data can be found in Annex 13.

Measles-rubella (MR) campaign evaluation

In Bangladesh, the FCE completed an evaluation of the Gavi-funded MR campaign. Detailed methods of the MR campaign evaluation can be found in Annex 5. The MR campaign evaluation aimed to answer two main questions:

1. What was the impact of the MR campaign on reducing susceptibility to measles and rubella
2. What was the impact of the campaign on routine immunization systems

In addition to a process evaluation, as described above, we implemented a range of quantitative data collection as part of a mixed-method approach. This involved the following components:

- Pre- and post-campaign household surveys, including dried blood spot assessment of immunological response to vaccination
- MR campaign vaccination session observations at Expanded Program on Immunization (EPI) centers and educational institutes
- Exit interviews with mothers or primary caregivers
- EPI service providers' survey

Pre- and post-campaign household surveys

The pre- and post-campaign household surveys collected data on the following topics:

- Socio-demographic characteristics of primary caretaker and child
- Knowledge about measles and rubella
- Vaccination status of children by recall and card documentation
- Experience at most recent routine EPI sessions, including unsuccessful vaccination attempts
- Access to vaccination services, demand-side constraints, and experiences at the health facility
- Registration experience with the MR campaign (post-campaign only)
- Experience at the MR campaign (post-campaign only)
- Opinions of the MR campaign (post-campaign only)

As part of the household survey in the Gavi FCE, we are implementing biomarker-based approaches using dried blood spots (DBS). DBS samples from a subset of respondents were analyzed to measure antibody responses to measles and rubella in both the pre- and post-campaign surveys to understanding the impact of the campaign in reducing population-level susceptibility to measles and rubella. Further details on the assay development process and standardization can be found in Annex 7.

MR campaign vaccination session observation at EPI centers and educational institutes

Observation at vaccination sessions provided information on how the campaign was implemented, including:

- Vaccination session opening and closing time
- Staff and volunteers available
- Number of expected children
- Number of children vaccinated (form extraction)
- Availability of vaccines and supplies
- Vaccine handling and administration, including cold-chain
- Motivational activities
- Supervision and monitoring

Exit interviews

By interviewing mothers or primary caregivers of children exiting the campaign sessions, we measured:

- Demand-side constraints
- Experience at the facility
- Vaccination knowledge, including knowledge of vaccines just received
- Waiting time
- Perceptions of mothers about services provided from the sessions

MR EPI service providers' survey

Immediately following the campaign, interviews were conducted with vaccinators about their experience preparing for and conducting the campaign. Specifically, this survey included:

- Experience implementing the MR campaign
- Workload during the campaign and ability to maintain routine immunization responsibilities
- Training and campaign knowledge
- Opinions and perceptions of the MR campaign

Secondary data analysis

This year, as part of the Gavi FCE we conducted a range of secondary data analysis to complement primary data collection efforts. The three main components are:

Small area estimation of vaccine coverage and under-5 mortality

To understand variation by geography in key indicators related to Gavi support, we systematically compiled and analyzed survey data to generate subnational estimates of coverage of five vaccines (Bacillus Calmette-Guérin [BCG]; diphtheria-pertussis-tetanus, three doses (DPT3); three doses of the oral polio vaccine (OPV3); measles vaccine; and the pentavalent vaccine, three doses), coverage of full vaccination (BCG, OPV3, DPT3, and measles vaccine), and under-5 mortality. Specifically, we estimate province, district, and in the case of Bangladesh, subdistrict (upazilas), trends in these indicators from 1990 to 2015, using small-area estimation statistical models that leverage relationships over both time and space. We've continued to develop and improve previously described methods¹¹ and a detailed description of the small area estimation methodology is available in Annex 2.

Inequality analysis by household wealth and sex

To further assess progress in reducing inequality, in addition to inequalities by geography, we also analyzed available survey data to determine vaccination coverage estimates for BCG, DPT3, OPV3, measles, and fully-vaccinated by sex and wealth quintile in each country. To estimate household wealth, we used a survey-specific asset-based measure. For each sex and each wealth quintile, a separate estimate is calculated for each survey at the national level available and localized in time to the average birth year of children in that cohort. We compare absolute differences and determine ratios of coverage between sexes and the top and bottom wealth quintiles. Detailed methods are described in Annex 4.

Analysis of administrative data on immunization coverage

In Mozambique, Uganda, and Zambia, we analyzed administrative data on immunization coverage to understand the scale-up following the national introduction of new vaccines. In Mozambique, this included data from the HMIS system, called *Módulo Básico*, as well as a parallel reporting system implemented by the National Immunization Programme (NIP). In Uganda, we relied on the Uganda National Expanded Programme on Immunisation (UNEPI)/World Health Organization (WHO) reporting system data. In Zambia we are in the process of compiling all HMIS data; in this report we analyze the HMIS data collected through the Zambia HFS.

As there are a range of data quality issues in the estimation of denominators in all three countries, we analyzed administrative data by comparing the ratio of the number reported to be delivered for the new vaccine (PCV or rotavirus vaccine) over the number reported to be delivered for pentavalent vaccine, for each of the corresponding doses. That is, we computed the ratio of first dose PCV to first dose pentavalent vaccine; second dose PCV to second dose pentavalent vaccine; and third dose PCV to third dose pentavalent vaccine. This provides a measure of whether the new vaccine is being delivered at levels comparable to vaccines, such as pentavalent vaccine, that are already in the system, and whether the drop-out rates are different from existing vaccines.

Mixed-method analysis

An important aim of the Gavi FCE is to maximize linkages between the different evaluation components described above and strengthen confidence in findings through triangulation of evidence. The prospective design lends itself to various opportunities for integrating evidence from the different data sources. Some examples are described here.

As previously noted, TOCs for each support stream provided an overarching analytical framework for both process evaluation and surveys, which provided a way to organize the interface of qualitative and quantitative evidence, and RCA of findings across the TOC milestones drew simultaneously on evidence from process tracking, KIIs, and survey data. TOCs also enabled cross-stream and cross-country comparison (e.g., parallels between PCV and rotavirus vaccine introduction in Zambia and parallels between HSS implementation across countries). This facilitated greater understanding about similarities and differences in how Gavi support is implemented, the roles played by Gavi partners in different contexts, and cross-cutting factors influencing the outcomes of support.

Qualitative and quantitative data were also integrated opportunistically in a sequential manner. In other words, process evaluation findings were leveraged to inform survey design and survey findings to inform process evaluation strategy. For example, results presented in the 2013 process evaluation of PCV

introduction¹² identified challenges with distribution of PCV fridge stickers, among other shortcomings, to be a critical bottleneck that hampered PCV readiness. HFS instruments were subsequently modified to include this and other indicators of PCV readiness. A reverse example occurred this year in Bangladesh. To summarize as an example of the sequential integration of mixed methods, findings from the campaign exit interviews in Bangladesh revealed low levels of registration, which flagged a priority area for in-depth investigation using qualitative approaches. Subnational KIIs helped illuminate that a short time-frame for registration and delays in the availability of prescribed forms led to health workers employing alternative methods for registration and ultimately to suboptimal estimates of the target population.

Presentation of findings

The remainder of this report presents our findings, organized into four country reports, followed by an analysis of common themes that have emerged across all of the countries.

The country reports are organized in four sections:

1. The **Gavi support section** provides a summary of Gavi support to each country
 - The findings section begins with a description of country demographics and national-level immunization-related characteristics including vaccine coverage and all-cause and cause-specific mortality.
 - In Mozambique and Uganda, we present results from the initial resource tracking work.
 - In all four FCE countries we present subnational-level (province, district, and subdistrict) estimates of vaccine coverage and under-5 mortality as well as measures of sex and wealth equality for vaccine coverage.
2. A **timeline** that highlights key activities for Gavi support streams that the FCE has tracked up to this reporting period.
3. The **stream-specific analysis** section lays out the core country findings organized by Gavi support stream using a number of different devices.
 - First, is a **summary of progress**, which details country progress and successes as well as challenges and responses regarding the implementation of a support stream. These data are organized in a table corresponding to the TOC milestones. Responses to process challenges that are indicated may either be successful or unsuccessful in outcome. As noted above, this includes data from both qualitative and quantitative methods, including evidence from analysis of secondary sources (e.g., HMIS coverage data on PCV from Mozambique reflecting routinization). Preliminary process tracking information is also presented for support streams that have yet to be implemented (e.g., inactivated polio vaccine [IPV]).
 - Second, is the **analysis of major challenges and successes**. This section reports key findings that were identified through RCA. For each finding, a corresponding RCA diagram is provided to visually summarize the causal chains that link root causes; contextual factors; and intermediate challenges, responses, and successes to consequences. Accompanying each RCA diagram is a section of analytical narrative that explains the RCA diagram with additional detail.

- Each finding leads to one or more **recommendations**, which the evaluation team proposes as course-correction for improving processes at varying levels and between levels (global, national, subnational). Recommendations may range from considerations on formal policy changes to clarifications of process; however, they do not address operational details for implementing recommendations, an additional step which is outside the scope of this evaluation.
- Considering the prospective design of the evaluation and the flexible, adaptive nature of data collection activities, the depth and breadth of the evidence base varies across findings. This variation signals the need to gauge the evaluation team's confidence in each finding. We, therefore, developed a **robustness ranking scale** to subjectively, but systematically assess robustness of findings with respect to three dimensions:

Triangulation refers to the breadth of qualitative and quantitative data sources (e.g., surveys, documents, key informants, etc.) that inform the same finding, where greater triangulation equates to more robust findings.

Where the finding lies on the *continuum between fact and perception*. This dimension complements triangulation in that factual information generally requires less triangulation in order to be considered robust. However, it is important to note that some of the evaluation questions are largely perception-based (e.g., the added value of partnership, or care-giver knowledge of disease) and rely on inferences based on more subjective than objective evidence. As long as these findings are supported by well triangulated data, they could be considered robust even though they based on more subjective evidence.

The *quality of the data* from each source is the third dimension, where high-quality data clearly contribute to greater robustness. Indicators of quality in qualitative data include, but are not limited to:

- Recentness (e.g., timing of interview or group discussion relative to topics discussed to minimize recall bias);
- Conditions of an interview or group discussion (e.g., rapport with respondent, interruptions, appropriate pacing, appropriate level of privacy for interview, balanced as opposed to one-sided group discussions); and
- Degree of proximity to the topic or event in question (e.g., first hand observation by the evaluation team or respondent's first-hand experience as opposed to second-hand information).

Indicators of quality in quantitative data include but are not limited to: reliability, timing, sample size, potential for selection or measurement bias, and potential for confounding in causal analysis.

Our robustness ranking does not systematically distinguish between qualitative and quantitative findings. Rather, each finding is assessed in terms of all relevant and appropriate data sources that inform the conclusion, whether the sources be exclusively qualitative or quantitative in nature, or a combination of both.

Using the dimensions above, we developed the following four-point scale as a general guide for ranking findings and for describing the rationale behind the ranking.

Ranking	Reason (generic)
A	The finding is supported by multiple data sources (good triangulation) which are generally of good quality. Where fewer data sources exist, the supporting evidence is more factual than subjective.
B	The finding is supported by multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation) of good quality but perhaps more perception-based than factual.
C	The finding is supported by few data sources (limited triangulation) and is perception-based, or generally based on data that are viewed as being of lesser quality.
D	The finding is supported by very limited evidence (single source) or by incomplete or unreliable evidence. In the context of this prospective evaluation, findings with this ranking may be preliminary or emerging, with active and ongoing data collection to follow-up.

- The **cross-stream findings** section rounds out each country report of findings. This section highlights cross-cutting themes that emerged from the stream-specific findings and provides more synthetic analysis. A conclusion statement then follows, which summarizes key findings from country and reflects on recommendations provided earlier and on positive and negative unintended consequences of Gavi support to country during this reporting period.

Chapter 2: Bangladesh

Bangladesh

Gavi support for Bangladesh

Bangladesh first received Gavi support in 2001. Among the various antigens offered in the Bangladesh routine immunization system, Bangladesh has, with Gavi support, introduced monovalent hepatitis B vaccine in its childhood vaccination schedule under routine EPI in 2003, replaced DPT and monovalent hepatitis B vaccines with pentavalent vaccine (DPT, hepatitis B, and *Haemophilus influenzae* type B [Hib] vaccines) in 2009, and introduced measles second dose (MSD) into its routine EPI program for 15-month-old children in 2012. With its own funds, the Government of Bangladesh (GOB) incorporated MR vaccine into its routine childhood vaccination schedule. With Gavi support, PCV is scheduled for introduction at the end of 2014 and IPV is expected to be introduced in 2015. Bangladesh also received Immunization Services Support (ISS) in 2001, 2003-2007, and 2010; Injection Safety Support (INS) from 2004-2006; and HSS support in 2009 and 2014.

Table 4: Overview of Gavi support in Bangladesh

Gavi support	Period of funding	Total amount of funding (US\$)
Pneumococcal conjugate vaccine (PCV)	2014-2016	79,491,000
Pentavalent vaccine	2009-2015	198,996,750
Human papillomavirus (HPV) vaccine	Demonstration project 2015	N/A
Measles second dose (MSD)	2012-2016	9,116,538
Measles-rubella (MR) vaccine campaign	2013	35,781,812
Measles-rubella vaccine, operational costs	2013	33,586,500
Health Systems Strengthening (HSS)	2010-2014 (with reprogramming of funds; application expected January 2015)	13,671,500
Inactivated Polio Vaccine (IPV)	2015-2016	18,859,500
Immunization Services Support (ISS)	2001-2004, 2006, 2009	23,340,200
Injection Safety Support (INS)	2004-2006	6,144,414
Vaccine Introduction Grant (VIG)	2001, 2008, 2012-2014	8,314,000

Source: <http://www.gavi.org/country/all-countries-commitments-and-disbursements>, accessed last April 21, 2015. Values shown represent Gavi commitments, those which Gavi intends to fund over the life span of the program, subject to performance and availability of funds.

Methods overview

Consistent with the prospective nature of the Gavi FCE, the evaluation reflects all Gavi supported-activities, assessing implementation and related milestones by support stream. Table 5 provides an overview of the methods used, the sources of data, and the topics assessed by these methods.

Table 5: Evaluation methods

Methods	Source consulted/study area	Topics investigated
Process tracking	<ul style="list-style-type: none"> - Collected and reviewed documents from different levels of the health system, including Gavi applications, Gavi decision letters, Expression of Intent (EOI), GOB letters, operational plans and budgets, meeting minutes of Interagency Coordinating Committee (ICC), Project Implementation Committee (PIC), Technical Sub Committee, and the Comprehensive Multi-year Plan (cMYP) - Observed meetings, including: advocacy meetings for MR campaign, launching ceremony of 21st NID, consultative workshop of MR campaign, and national and divisional level training of trainers (TOT) for PCV introduction. 	<ul style="list-style-type: none"> - Information was collected based on relevant TOC milestones for MR campaign, HSS, PCV, IPV and HPV.
Key informant interviews (KIIs)	<ul style="list-style-type: none"> - Conducted 58 country-level KIIs at different levels, from national to subdistrict level, with government personnel, non-governmental organizations (NGOs), WHO, and UNICEF. - Conducted nine KIIs with global-level staff from the Gavi Secretariat and Alliance partners. 	<ul style="list-style-type: none"> - Information was collected based on the relevant TOC milestones for MR campaign.
Pre-MR campaign household survey (HHS)	<ul style="list-style-type: none"> - Representative survey performed in one high-performing and one low-performing division. From these two divisions, the highest-performing district from the high-performing division and the lowest-performing district from the low-performing division were selected. The team also selected one city corporation from each of the two divisions, based on their low and high performance in EPI coverage. 	<ul style="list-style-type: none"> - Vaccination coverage - Knowledge, attitudes, practices about immunization - Basic socio-economic and household demographic information - DBS measurement of vaccine antibodies
MR campaign vaccination session observations	<ul style="list-style-type: none"> - Campaign sessions were observed in both rural and urban areas of 	<ul style="list-style-type: none"> - Vaccination session opening and closing time - Target children in the sessions

	<ul style="list-style-type: none"> - two (high- and low-performing regions) areas of Bangladesh - Observation in both routine EPI centers and educational institutes where campaign was implemented. 	<ul style="list-style-type: none"> - Attendance of children for vaccination - Availability of vaccine and other logistics - Motivational activities - Quality control - Supervision and monitoring
MR campaign exit interviews	<ul style="list-style-type: none"> - Exit interviews were conducted with mothers at facilities where the campaign was carried out. 	<ul style="list-style-type: none"> - Demand-side constraints - Experience at the facility - Vaccination knowledge - Waiting time - Mothers' perception about services provided at sessions
MR campaign EPI service providers' survey	<ul style="list-style-type: none"> - Immediately following the campaign, interviews were carried out with vaccinators. - Service providers' survey was conducted in the above-mentioned two divisions. 	<ul style="list-style-type: none"> - Experience implementing the MR campaign - Workload during the MR campaign - Training and campaign knowledge - Opinions of the MR campaign - Perceptions about the campaign
Post-MR campaign household survey	<ul style="list-style-type: none"> - Nationally representative survey, with intentional over-sampling in the same districts of the baseline HHS, to allow pre-post comparison 	<ul style="list-style-type: none"> - Vaccination coverage - Knowledge, attitudes, and practices (KAP) about immunization - Basic socio-economic and household demographic information - Experience with the MR campaign - DBS measurement of vaccine antibodies
Small area analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey and census data sources. 	<ul style="list-style-type: none"> - Estimation of district- and upazila-level vaccine coverage and under-5 mortality
Inequality analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey data sources of household wealth and vaccination coverage 	<ul style="list-style-type: none"> - Estimation of vaccine coverage differences by wealth quintile and sex

Findings

The FCE compiled and systematically analyzed relevant data to estimate key indicators at the national and, when possible, subnational level (Table 6,

Table 7 and Table 8). Table 7 outlines background country demographic and socio-economic characteristic, Table 8 shows estimates of vaccination coverage from multiple sources, and Table 8 shows estimates of under-5 and adult mortality.

Table 6: Country characteristics of Bangladesh

Characteristic	
Demographic and economic indicators	
Total population (2013)	156.6m
Birth cohort (2013)	3,122,310
Gross domestic product (GDP) per capita (2014)*	US\$625.34
Health spending and development assistance for health (DAH)**	
Government health expenditure as source (GHE-S)	US\$1.39B
DAH, channeled through government	US\$72.6M
DAH, channeled through non-government entities	US\$208M
Total DAH	US\$281M

*GDP per capita source: IHME covariates database, reported in 2005 international dollars

** Health expenditure is explained in terms of government health expenditure as source (GHE-S), DAH channeled through government (DAH-G), and DAH channeled through non-government entities (DAH-NG). GHE-S + DAH-G gives the total government health expenditure, GHE-S + Total DAH gives total spending on health in the country. Health expenditure estimates 2011; Gavi disbursements are total disbursements by calendar year, 2001–2015.

Table 7: Vaccine coverage estimates in Bangladesh

Vaccine coverage	Most recent survey estimate*	WUENIC 2013 revision**	Self-reported coverage (WHO)***
DPT/Penta3 coverage	92 %	97%	92%
DPT1—DPT3 dropout rate		2%	7%
BCG coverage	99.3%	99%	99%
OPV3 coverage	91.6%	97%	92%
Measles coverage	85.5 %	93%	89%
Percent fully vaccinated****	80.7%	N/A	N/A

* Most recent survey coverage estimates from 2013 CES

** WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) 2013¹³

***WHO vaccine-preventable diseases monitoring system, 2014 global summary¹⁴

**** BCG, measles, and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth).

Table 8: Child, adult, and vaccine-preventable disease mortality in Bangladesh

Child, adult, and vaccine-preventable disease mortality	GBD2013*
All-cause mortality (risk per 1,000)	
Infant mortality (_{1q0})	33.5 (30.1, 37.6)
Under-5 mortality (_{5q0})	40.8 (36.9, 45.4)
Female adult mortality (_{45q15})	149.5 (114.6, 188.0)
Male adult mortality (_{45q15})	192.1 (147.5, 237.9)
Cause-specific mortality: children under 5 (rate per 100,000)	

Measles	4.6 (2.2-8.2)
Diphtheria	0.01 (0.00-0.05)
Tetanus	0.1 (0.0-0.7)
Pertussis	4.9 (0.0-26.2)
Meningococcal infection	0.6 (0.3-1.0)
Diarrheal disease	11.3 (6.3-18.6)
Lower respiratory infections	97.4 (76.1-121.7)
Cause-specific mortality: all ages (rate per 100,000)	
Cervix uteri cancer	2.4 (1.6-3.5)
Acute hepatitis B	2.6 (1.6-3.8)
Cirrhosis of the liver secondary to hepatitis B	4.3 (3.0-6.1)
Liver cancer secondary to hepatitis B	3.8 (1.9-6.1)

* Mortality based on Global Burden of Disease (GBD) 2013 estimates

Analysis of immunization coverage, child mortality, and inequality

We systematically compiled and analyzed available data sources to estimate immunization coverage and under-5 mortality by geography, household wealth, and gender. These estimates should be interpreted with caution. In some cases different surveys give disparate results, suggesting data quality issues. Additionally, not all data are identified at the lowest geographic level.

In Bangladesh, the national estimates of vaccine coverage (Table 7) masked variable coverage rates within the country as shown in Figure 2 and Figure 3. DPT3 vaccination coverage increased in every district between 2000 and 2013, and exceeded 90% in all districts. By contrast, coverage of the fully vaccinated child was more diverse and remained at comparatively lower levels. Districts in Chittagong, and Sylhet divisions tended to have the lowest coverage of full vaccination. Annex 3 provides district level maps for 2000 and 2013 for all antigens (BCG, measles, DPT3, three doses of pentavalent, and OPV3).

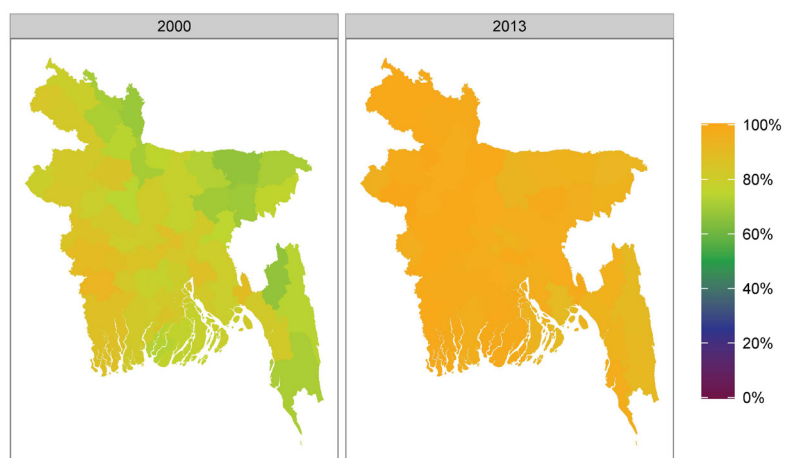
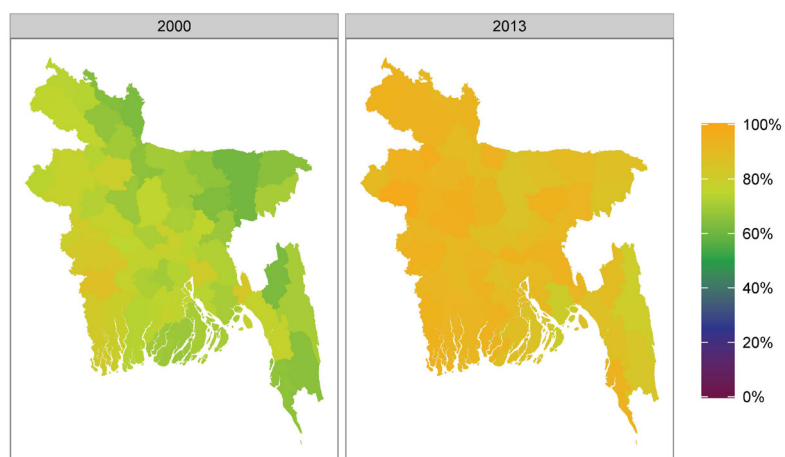
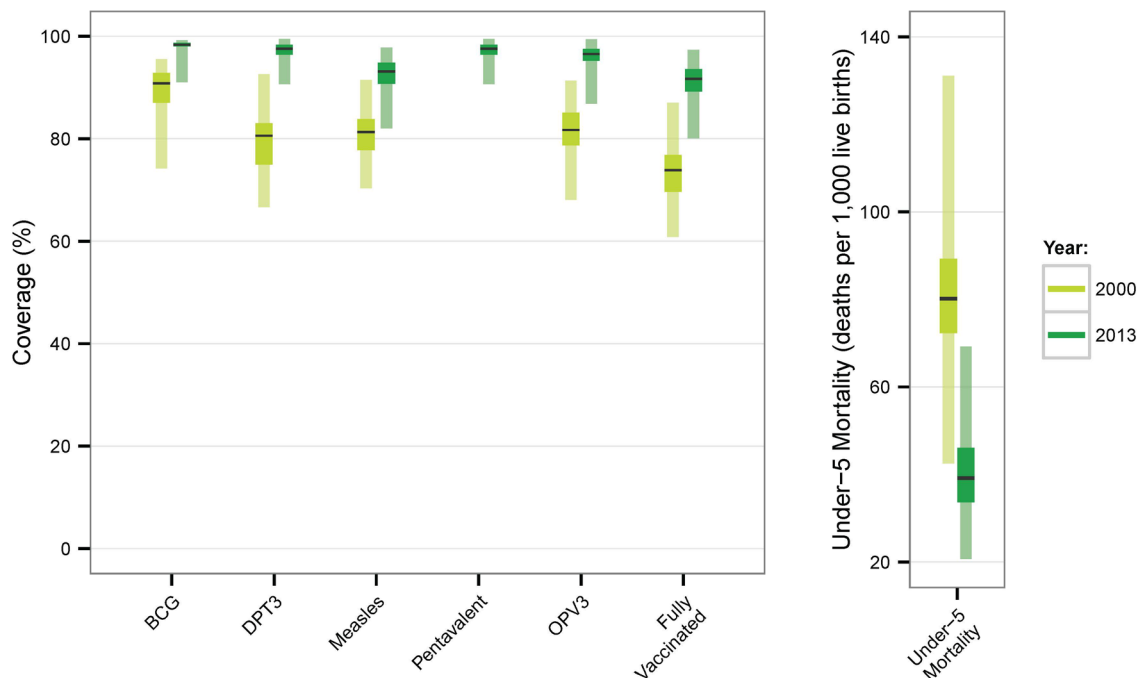
Figure 2: District-level DPT3 coverage in Bangladesh, 2000 and 2013**Figure 3:** District-level fully-vaccinated child coverage in Bangladesh, 2000 and 2013

Figure 4 summarizes the distribution of district-level estimates of vaccine coverage for 2000 and 2013 across vaccine antigens. These results emphasize the sizeable improvements in the median coverage across all antigens at the district level. These results also highlight reductions in geographical inequality, as measured by the range and interquartile range of coverage across districts. Almost all districts had at least 80% coverage for full childhood vaccination in 2013. Most districts achieved coverage greater than 90%.

Figure 4: Distribution of district-level vaccine coverage and under-5 mortality in Bangladesh, 2000 and 2013

The horizontal line represents the median across districts. The thick vertical bar represents the interquartile range, while the thin vertical bar represents the range across districts.



In addition to district-level estimates, we generated upazila-level estimates of vaccine coverage over time. Figure 5 and Figure 6 show maps of upazila-level estimates of DPT3 coverage and full vaccination coverage in 2000 and 2013. These maps show that considerable variation in vaccine coverage remains even within districts. Outlier upazilas could be a focus of studies to confirm and understand the drivers of lower immunization coverage. Additionally, these outlier upazilas might be more specific targets of health system strengthening activities to close gaps. Figure 7 confirms the reduction of upazila-level inequality, as measured by the range and interquartile range, across all antigens. Annex 3 provides upazila-level maps for 2000 and 2013 for all antigens (BCG, measles, DPT3, three doses of pentavalent, and OPV3).

Figure 5: Upazila-level DPT3 coverage in Bangladesh, 2000 and 2013

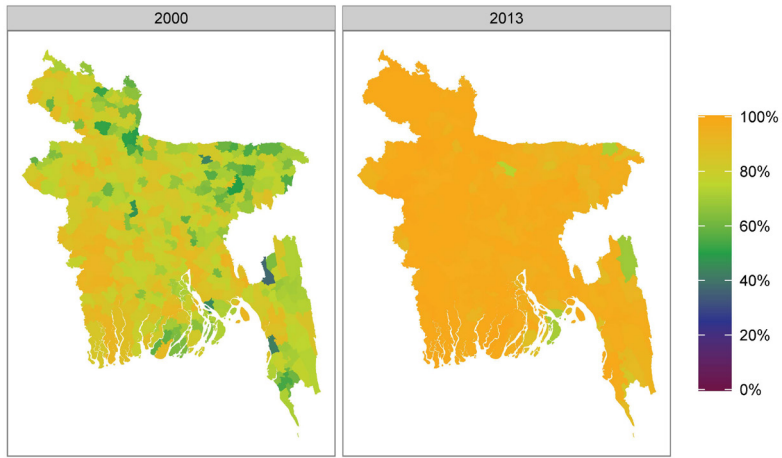


Figure 6: Upazila-level fully-vaccinated child coverage in Bangladesh, 2000 and 2013

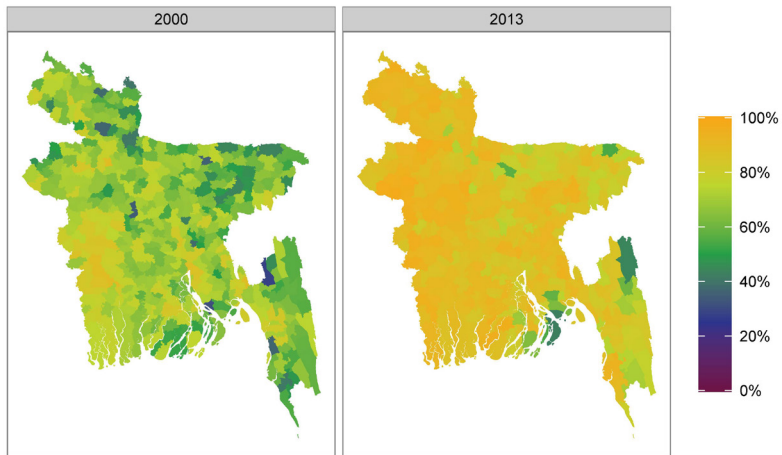
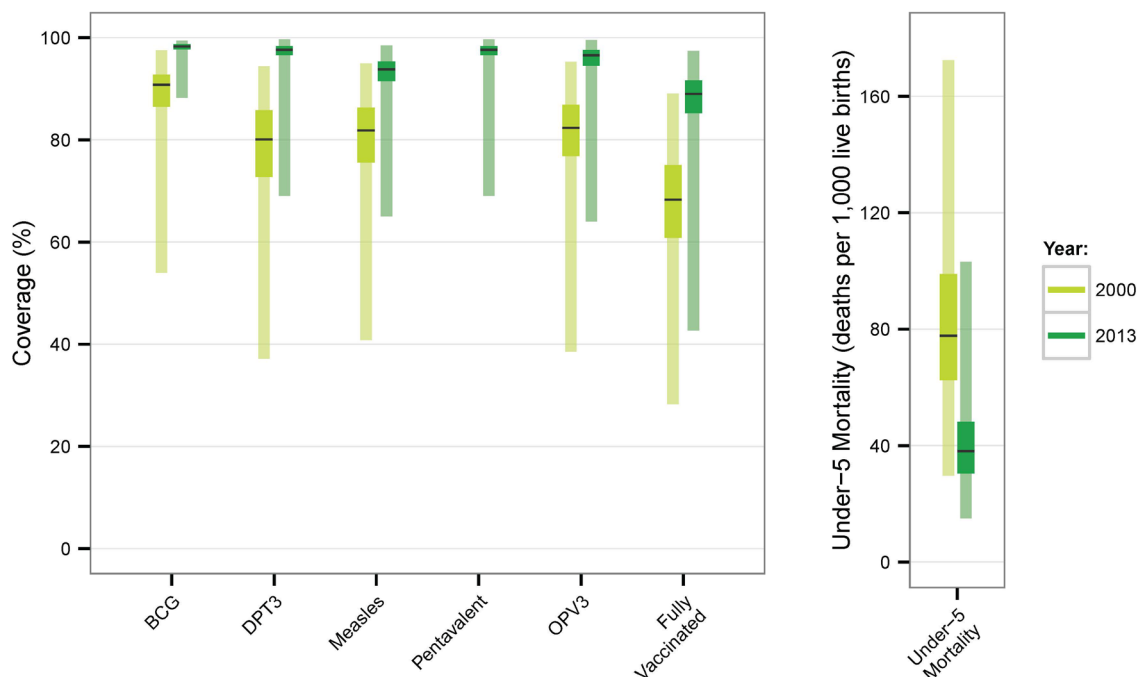


Figure 7: Distribution of upazila-level vaccine coverage and under-5 mortality in Bangladesh, 2000 and 2013

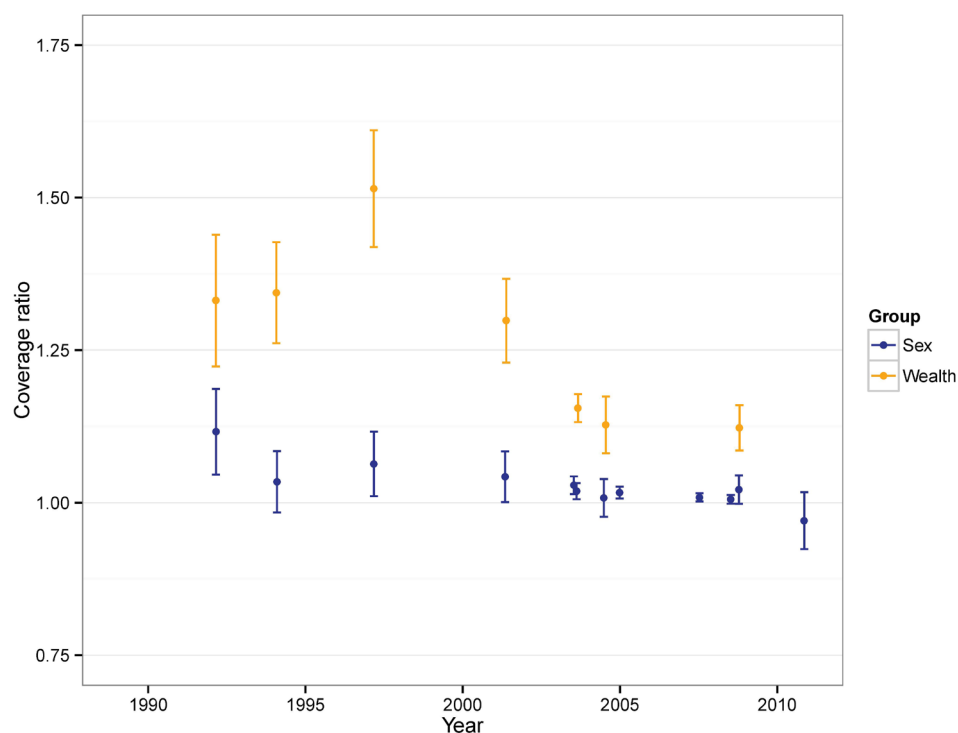
The horizontal line represents the median across upazilas. The thick vertical bar represents the interquartile range, while the thin vertical bar represents the range across upazilas.



In addition to geographical inequality, we observed inequality by household wealth (Figure 8). While the ratio of DPT3 coverage in the richest quintile compared to the poorest quintile declined over time, this ratio remained significantly above one based on the latest survey with available wealth index information. Figure 8 also shows that there were improvements in gender equality with respect to DPT3 coverage over time. While the latest survey indicated a male-to-female ratio above one, the confidence interval contained one.

Figure 8: Equity ratios of DPT3 coverage in Bangladesh

Wealth ratio is the ratio of DPT3 coverage in the richest quintile to coverage in the poorest quintile. Sex is the ratio of DPT3 coverage in males versus females.



National estimates of under-5 mortality (Table 8) mask considerable variation in district and upazila-level under-5 mortality in Bangladesh, as shown in Figure 9 and Figure 10. Between 2000 and 2013, all districts experienced a decline in under-5 mortality. However, there were both districts and upazilas where under-5 mortality remained noticeably higher than in other parts of the country. These areas were concentrated in the Sylhet and Barisal divisions, as well as in the northern part of the Dhaka division. Many of the areas with elevated under-5 mortality were also those with lower than usual vaccine coverage. Figure 9 and Figure 10 highlight the reduction in geographical inequality in under-5 mortality at both the district- and upazila-level.

Figure 9: District-level under-5 mortality in Bangladesh, 2000 and 2013

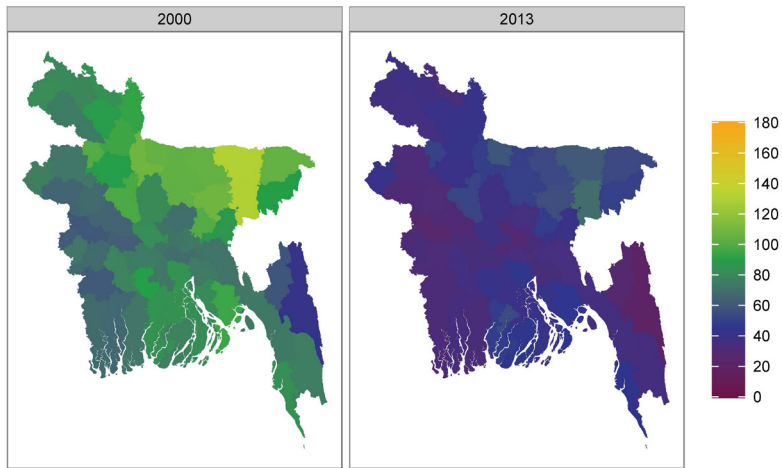
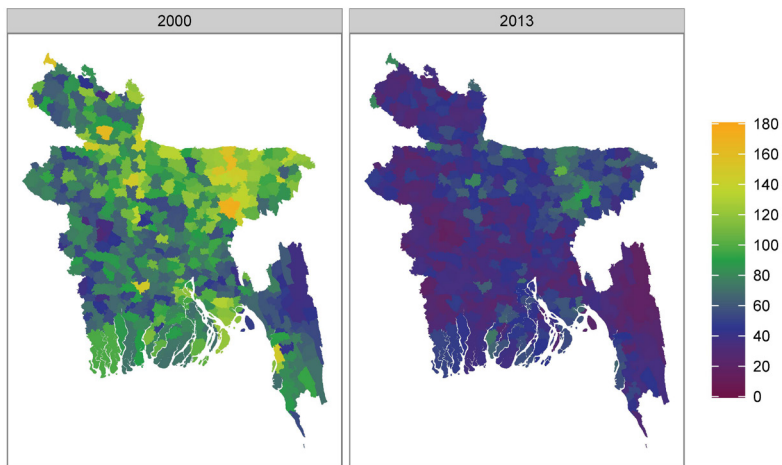
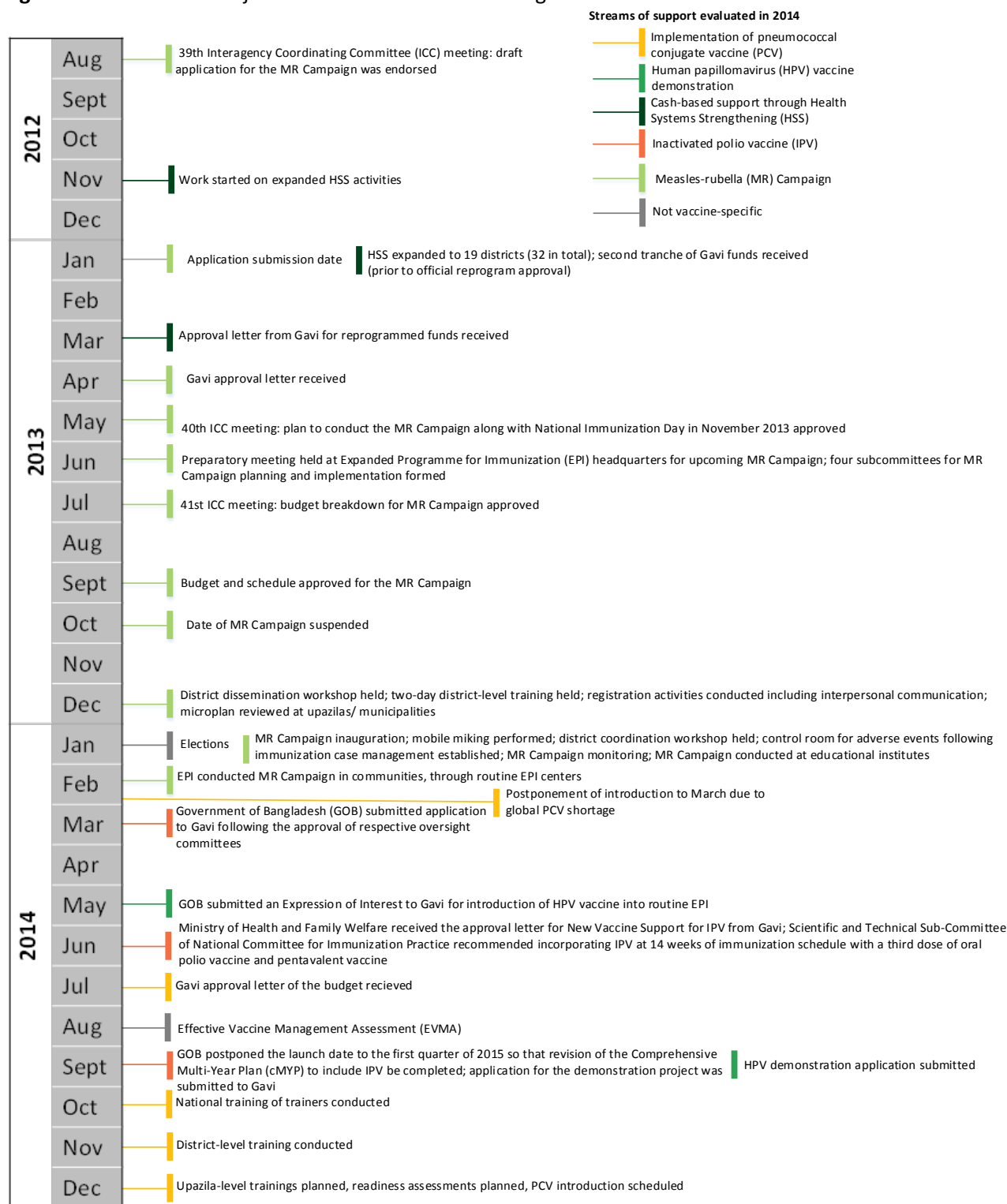


Figure 10: Upazila-level under-5 mortality in Bangladesh, 2000 and 2013



Overview of major immunization events

Figure 11: Timeline of major immunization events in Bangladesh*



* GOB submitted the NVS PCV application in May of 2011; Gavi approved the application in April 2012 for the period of 2013-2016. GOB submitted HSS proposal in March 2008. In 2009 the first tranche of HSS funds were received. No HSS funds were used in 2010. In 2011 Gavi requested reprogramming of HSS funds.

Measles-rubella (MR) campaign

Gavi provided support for the MR campaign in Bangladesh in 2013, which supplemented the introduction of routine MR vaccination. The Ministry of Health and Family Welfare (MOHFW) of the GOB implemented the national MR campaign in January 2014, targeting more than 52 million children between 9 months to under 15 years of age. The MR campaign was conducted nationally and to date is the largest MR campaign conducted globally.

A detailed description of the methods and results are described in Annex 5 and Annex 6. We report here on the key findings of this evaluation of the MR campaign. Figure 11 indicates the key events over the period of the MR campaign implementation. Table 9 summarizes the major progresses, successes, challenges, and successes of the MR campaign.

Summary of country progress

Table 9: Summary of country progress

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Appropriate MR campaign design	
<ul style="list-style-type: none"> - Use of evidence. Surveillance data on measles and rubella disease burden were used to inform and refine the design of the campaign. - Multiphase, age-specific strategy. A two-phase strategy was used to reach the target population of 52 million children, ages nine months to less than 15 years: week one activities targeted ages five to less than 15 and were carried out in schools; weeks two and three targeted children less than five and were held in routine EPI centers. - Catching school drop-outs. The EPI sessions were also intended to serve school-aged children who do not attend school (<i>MR campaign Planning and Implementation Guide</i>). Based on exit interviews, more than 20% (123/574) of children vaccinated at EPI centers were of school age (greater than 5 years) in the selected high- and low-performing divisions. In the post-campaign survey covering all divisions, 10.5% (304/2,901) of children who attend school and received MR vaccine during the campaign through routine EPI centers. - Avoiding disruption of routine EPI services. The MR campaign design aimed to not disrupt routine EPI activities, (<i>national and subnational level KII</i>) by maintaining delivery 	<ul style="list-style-type: none"> - Insufficient time period for school based vaccination. The one-week timeframe for the school-based campaign, targeting one school each day, was insufficient, particularly at sites with high target numbers (over 1,000 children in three sessions; Annex 6, Table E, Table F). However, health workers and first-line supervisors responded in some cases by merging two sessions together to more effectively manage the brief time window. This enabled health workers to save time on travel and planning, as they would have otherwise worked at multiple locations that day (<i>subnational KII</i>). - Catch-up vaccination for other antigens. The MR campaign was not explicitly designed to catch up on other antigens.

<p>of routine EPI services two days per week, and conducting the campaign sessions four other days per week (<i>MR campaign Planning and Implementation Guide</i>).</p>	
<p>Timely and adequate planning and budgeting</p>	
<ul style="list-style-type: none"> - Use of partners' expertise. Partner organizations (WHO, UNICEF) provided key technical assistance in planning and budgeting. - Timely updates to changing plans. The MR campaign implementation plan was updated in a timely manner by communication through letters from the national-level to the subnational-level and by updating information and instructions prior to the launch of the campaign. 	<ul style="list-style-type: none"> - Short time before award disbursement. The six-month time window for completing all preparatory activities between Gavi's award decision and the campaign implementation was not adequate. In response, a consultant was hired by UNICEF to prepare the MR campaign guide and carry out other preparatory activities. Additionally, a short term consultant was hired by WHO to carry out preparatory work. - Gaps in coordination. Top-down budgeting created gaps in coordination between planning and budgeting, although, a technical subcommittee was formed and developed a detailed budget breakdown based on the necessities for implementing all the required activities under MR campaign (<i>National level KII and document review</i>). - Alignment with country plans. The cMYP and the Operational Plan (OP) of Maternal Neonatal Child and Adolescent Health (MNC&AH) were not updated with the inclusion of the MR campaign prior to the submission of the application. It should be noted that MR vaccine was included as part of the routine EPI in the cMYP.
<p>Timely approval by concerned authorities</p>	
<ul style="list-style-type: none"> - Interagency Coordination Committee (ICC) approval. ICC approved the event calendar and the budget for launching the MR campaign in November 2013. - Revision of the OP and updating of the PIP. To avoid lengthy administrative procedures for approval by the Executive Committee of National Economic Council (ECNEC) the health minister took alternative measures to allow implementation to proceed 	<ul style="list-style-type: none"> - Budget approval. The MR campaign budget was not reviewed or approved by the ECNEC because the Steering Committee, headed by the Health Minister, revised the existing approved OP of MNC&AH to incorporate the major line items of MR campaign. This intersectoral adjustment resulted in the MR campaign being funded without exceeding the approved OP budget; consequently the budget was not reviewed and approved by ECNEC. - Campaign rescheduling. Political unrest and other factors posed challenges to meeting the original launch date of November 2013. In response, the EPI rescheduled the MR

campaign launch for the end of January 2014.	
Sufficient funding available in time	
<ul style="list-style-type: none"> - Gavi disbursement. Gavi disbursed the full amount of the MR campaign funding on time. - Distribution to regions. The funding was made available at the district and subdistrict levels. - Payment of health workers. Ninety nine percent of respondents on the providers' survey received an allowance, 91% received refreshments, and less than 1% received nothing (EPI Provider Survey). 	<ul style="list-style-type: none"> - Volunteers expected more budget for their refreshment. From subnational level KII it was found that the amount of money allotted for volunteers' refreshments made them reluctant to participate in MR campaign sessions. To ensure the participation of the volunteers in the sessions concerned health workers spent extra money from their own resources. - The EPI program could not spend the entire Gavi grant, but only spent the Gavi funds which were most necessary to carry out the MR campaign.
Population enumeration and district microplanning	
<ul style="list-style-type: none"> - Microplanning. Microplans were reviewed and updated prior to the campaign. - Population enumeration. MR vaccination target numbers were projected from the Geographic Reconnaissance (GR) report. These estimated target numbers were then to be confirmed through door-to-door registrations in the communities and schools. 	<ul style="list-style-type: none"> - Microplanning training and logistics. Microplanning was included in the two-day health worker training schedule for MR campaign. However, some workers mentioned that time allocation for microplanning topic was short, and they suggested increasing the duration of training to three days. Most health workers reported receiving two days of training (83%), with 15% receiving only a single day of training (Annex 6, Table N). Microplanning forms were also not provided on time, creating additional strain on health workers. However, health workers' motivation and flexibility and experience gained during earlier immunization campaigns enabled them to efficiently complete microplanning in time (<i>subnational level KII</i>). - Challenges in carrying out registration. Interpersonal communication (i.e., going door-to-door and speaking directly with mothers/caregivers in communities) was not always feasible, particularly in hard-to-reach areas. As a result, less than 20% of mothers reported that a health worker talked with them about registration (Annex 6, Table AA). In response, health workers instead assessed the target population in other ways for example from EPI registers and <i>bari</i> (neighborhood) heads (<i>subnational level KII</i>).

	<ul style="list-style-type: none"> - Low target numbers at some sites. The target number of children for the MR campaign was less than 100 at 7% of school campaign sessions (5/72) (Annex 6, Table E) and 51% of EPI sessions (37/72) (Annex 6, Table F).
<p>Timely and sufficient procurement of vaccines and commodities</p>	
<ul style="list-style-type: none"> - Procurement of MR vaccine. UNICEF procured sufficient MR vaccine prior to the start of the campaign. - Procurement of other supplies. Other commodities, including auto-dispensing syringes and safety boxes, were procured prior to the campaign by the government using the standard procurement systems. WHO also supplied equipment for marking children's fingers after they had been vaccinated. 	<ul style="list-style-type: none"> - Logistical supplies: quality and availability. In some cases there were inadequate quantities of soap, finger markers, and/or cotton (Annex 6, Table H). Some supplies of were also of low quality; for example, some of the finger markers were expired and thus less functional. - MR vaccines and syringes. Stock-outs of MR vaccine and/or syringes did occur at some sessions (12/72 educational sessions and 10/72 EPI sessions based on our facility observation). However, in all but three routine EPI sites, and in all but two school-based instances, health workers were able to successfully call for backup supplies from nearby centers or city corporation offices and complete the session (Annex 6, Tables C and D).
<p>Cold-chain and logistic system prepared for MR campaign</p>	
<ul style="list-style-type: none"> - Cold-chain. Preparation of cold storage for the MR vaccine and other logistics was carried out at the district and subdistrict level. - Other logistical supplies. Diluent and syringes were available at all sessions (Annex Table H). 	<ul style="list-style-type: none"> - Cold-chain: storage facilities. Standard available government and health system infrastructure for vaccine storage was insufficient at national level. However, campaign implementers at the national-level were able to use other public sector facilities. Subnational-level implementers coordinated and collaborate with local power departments and ice cream factories to prepare frozen ice packs to carry the vaccine through vaccine carriers to the sessions. These adjustments helped maintain the cold-chain at all levels (national-level KII). - Cold-chain: vaccine carriers. Dial thermometers were not available to monitor the temperature of the vaccine carriers. However, vaccine vial monitors were used to ensure the quality of the vaccines. Freeze tags were used to monitor ice lining refrigerator temperature.

	<ul style="list-style-type: none"> - Cold-chain: ice packs. The correct type and necessary quantity of ice packs were not always adequate; in some cases, ice packs in the vaccine carriers were not fully frozen (between 6 and 61% of the time across urban and rural strata) and in 6% of sessions in Sylhet (rural) the packs were fully melted (Annex 6, Table I). - Other logistical supplies. Based on the facility assessment, MR vaccine vials and carriers were available in 100% of the facilities except in Rajshahi CC (94% vaccine vials, and 89% vaccine carriers) (Annex 6, Table H).
Campaign monitoring systems are available	
<ul style="list-style-type: none"> - Multilevel monitoring system. A two-level, multi-departmental monitoring system was established, with first- and second-line supervisors and medical and non-medical departments. - Checklists. Monitoring checklists were developed prior to the campaign. - AEFI Monitoring. Special medical teams were formed to monitor AEFI case management during the campaign. Facility observations indicated that the few AEFIs that occurred were reported promptly (Annex Table J). 	<ul style="list-style-type: none"> - Forms frequently unavailable. A number of monitoring forms were frequently unavailable to first line supervisors (subnational-level KII). Registration forms were only supplied at 53% of EPI sessions and 19% of school-based sessions based on the facility observation, and supply forms and tally sheets were also inconsistently available (Annex 6, Tables F and E). However, health workers were able to improvise forms during the campaign. - Supervision. First-line supervisors were unavailable in many sessions (60% of routine EPI sessions observed and 35% of school-based sessions observed; see Annex 6, Table G). EPI session observation data revealed that second-line supervisors were not available in most of the observed vaccination sessions (five second-line supervisors were found in 144 observed sessions). This was partially due to insufficient transportation stemming from political unrest. In some cases, second-line supervisors were able to use their own vehicles. Some monitoring was also carried out through mobile phone communications. It was reported through KIIs that in the absence of first-line supervisors, experienced vaccinators performed supervisory duties, taking up these additional responsibilities (<i>subnational- level KII</i>). For example, reports were appropriately sent at the end of

	<p>campaigns, regardless of supervisor presence (99%; 143/144).</p> <ul style="list-style-type: none"> - Effect of monitoring on routine EPI. Campaign monitoring activities detracted from routine monitoring by first-line supervisors, with greater demand on health workers' time, and limited availability of other vaccines (Annex 6, Tables A, and B).
Adequately skilled health workers are available	
<ul style="list-style-type: none"> - Training: curriculum development. A cascading training curriculum was developed prior to the campaign. - Training implementation. EPI HQ conducted the Training of Trainers (TOT) and other trainings in September 2013. District- and subdistrict-level trainings were conducted in December 2013. More than 99% of service providers in the original four surveyed areas received training, and 83.3% of EPI providers reported receiving at least two days of training (Annex 6, Table N). - Multisectoral involvement. The involvement of health workers from multiple sectors ensured an adequate workforce for the MR campaign. - Health worker skills. Based on facility observations, vaccinators demonstrated high levels of use of non-touch technique (98% to 100%) and disposal of used AD syringes into the safety box (94% to 100%) (Annex 6, Table K). 	<ul style="list-style-type: none"> - Training curtailed. Training programs at the district and subdistrict level were deferred multiple times due to political unrest (<i>hartals</i>) and the length of training was curtailed. The specific training duration was two days, however, 15% (23/156) had only one day. Only 55% of EPI staff considered their training adequate. Reasons cited for inadequate training included that it was too short (100%) and, less commonly, that methods and/or trainers were not good (3% and 10%, respectively) (Annex 6, Table N). - Health worker skills. Facility observations revealed that some standard vaccination practices were not always followed, including hand washing before vaccination (5% to 73%), snug placement of top of vaccine carrier (68% to 98%), marking fingers (47% to 100%), tallying each vaccinated child (54% to 100%), and providing information on side effects (2% to 9%) (Annex 6, Table K). - Increased demand for skilled health workers. Low numbers of skilled vaccinators were observed in some sessions, with an average ratio of up to 121 children vaccinated per number of eligible vaccinators in school-based sessions in Sylhet community clinic (CC) (71-84 in the other three original survey areas (Annex 6, Table E). This also resulted in a higher workload; more than a third of vaccinators (53/156) worked nine more hours per day than during a typical EPI campaign day. However, the vaccinators who had been involved in the previous MR campaign utilized their skills in vaccinating high numbers of children. Their previous experiences helped vaccinators to deliver vaccinations to as many as 400 children in

	one session (double the originally planned target of 200 children per vaccinator) (Annex 6, Tables E and F).
Sufficient number of vaccination points prepared and supported	
<ul style="list-style-type: none"> - Identification of vaccination points. Vaccination points were identified prior to the campaign through microplanning, based on routine EPI session information, including some other outreach centers and all schools/educational institutes for school campaign. - Preparation of vaccination points. Volunteers were oriented prior to campaign. Vaccination points in schools were prepared for sessions by bringing the necessary resources to the site, choosing a separate classroom, putting up the <i>moni flag</i>, and preparing a table with the necessary vaccination supplies. School teachers were oriented to provide support as volunteers through a one day orientation program at district/CC/subdistrict level. - Support of vaccination points. Volunteers were available to provide support at 75% (54/72) school sessions, and 69% (50/72) EPI based sessions. Waste disposal was managed by the vaccinators. Nearby buffer stock sites provided support in case of stock-outs of supplies. 	<ul style="list-style-type: none"> - Sessions longer than expected. Some sessions were unable to be carried out according to the plan, particularly in rural areas. Sessions took longer time than expected and/or did not have sufficient volunteers. <ul style="list-style-type: none"> o Facilities assessment data indicate that at the 72 school sessions observed, the longest session was 6 hours 18 minutes. o Some sessions had as few as one volunteer, and some sessions had as many as 390 children per volunteer. - Frontline supervisors and vaccinators were able to improvise the vaccination plan in order to complete school campaign in the specified time period. The duration of the campaign was extended one or two days in some areas, in consultation with authorities, in order to cover left-out schools (<i>subnational- and community-level KII</i>). - Large populations at some school sessions. Target populations were very large at some schools, making it difficult for vaccinators to complete multiple sessions in a day as originally planned. Therefore, some schools of different sizes were combined into a single location to manage the large population. The same teams were assigned to perform the vaccination on the same day, based on the locations and the size of the target population; this strategy proved efficient, as it reduced time required for organization as well as travel time (<i>community-level KII</i>).
Adequate demand for MR generated	
<ul style="list-style-type: none"> - Multilevel, multifaceted approach to generating demand. A coordination committee was formed at every administrative level and an advocacy strategy was developed. This included distribution of information, education and communication (IEC) materials prior to the campaign, involvement of the media and celebrities, text messaging via cell phone, and the use of interpersonal communication to both 	<ul style="list-style-type: none"> - Generating demand. There were many challenges to generating demand for MR, particularly in more remote areas, such as delay of advocacy-related events, unavailability of IEC materials, and incomplete coverage of local-level interpersonal communication. However, word-of-mouth (from relatives and neighbors) and mosque miking announcements occurred in most areas and

<p>generate demand and carry out registration (<i>document review and national-, subnational-, and community-level KII</i>).</p> <ul style="list-style-type: none"> - Increased awareness of measles. Awareness of measles increased in each of the original four districts/city corporations due to the campaign, according to comparisons of pre- (measles: 83% to 99% awareness) and post-campaign surveys (measles: all great than 99% awareness) (Annex 6, Table AA). - Widespread awareness of and belief in MR campaign. In the post-campaign survey, more than 98% of caregivers surveyed knew about the MR campaign (Table BB) and less than 1% of caregivers believed that the MR campaign had no benefit (Annex 6, Table DD). 	<p>were effective in raising awareness. According to the post campaign survey, “word-of-mouth from relatives” and “announcements made in the area” were most often reported as ways that people heard about the campaign (66% and 52% of interviewees respectively), in addition to 64% of respondents hearing from the campaign from health assistants/vaccinators (Annex Table M). Exit interviews also highlighted the importance of word-of-mouth, community announcements, and health assistants (Annex Table L) in demand generation.</p> <ul style="list-style-type: none"> - Vaccine resistance. Rumors of poor quality vaccines and serious adverse effects of vaccination were reported at the community-level, posing challenges in generating demand (<i>subnational-level KII</i>). For example, SMS were sent from an unknown number, trying to create panic; however, instant initiatives from law enforcement agencies helped to reduce the rumors and motivate people (<i>national-level KII</i>). Based on the post-campaign survey, of the 10% of caregivers who reported non-vaccinated children, around a third chose not to vaccinate because of fear of side effects (Table 10). <p>Limited awareness of rubella. Awareness of rubella remained relatively low after the campaign (15%), but it increased substantially compared to before the campaign (Annex 6, Tables AA and BB). This may be a reflection of the lack of a local language equivalent for rubella in contrast to measles.</p>
<p>Sufficient volume of quality vaccine available</p>	
<ul style="list-style-type: none"> - Vaccine availability. Sufficient volume of vaccines were available prior to the campaign at the national level. - Supply availability. Overall, greater than 90% of campaign sessions had adequate supplies of MR vaccine and syringes to meet demand without having to call for backup supplies (Annex 6, Tables C, D, and E). - Buffer stock. Buffer stock was available from the national to the community level. 	<ul style="list-style-type: none"> - Socio-political factors. Vaccines and supplies could not be distributed in a single batch in each district from the national level as initially planned. Political unrest restricted the movement of transports from the national level to the districts, which disrupted the distribution plan. In response, EPI developed a contingency plan, instructing district authorities to send hired vehicles to EPI HQ in between strike periods

	<p>to collect the necessary vaccines and supplies. EPI HQ used WHO vehicles to distribute supplies to some districts, which ensured transport of materials and maintained the campaign schedule.</p> <ul style="list-style-type: none"> - Stock-outs. Stock-outs of MR vaccine, AD syringes, or both occurred in 14% (10/72) of observed EPI sessions and 16% (12/72) of observed school-based sessions. In response, backup supplies were obtained in all but three Routine EPI sites and two school-based sessions of these instances (Annex 6, Tables C and D).
<p>Timely access to accurate information on implementation status</p>	
<ul style="list-style-type: none"> - Timely updates on changes. EPI HQ updated involved parties about the postponed schedule, and rescheduling of campaign, in a timely manner. - Reporting system developed at multiple levels. A separate Management Information System (MIS) was developed to implement the campaign. Two MIS forms were developed and distributed to the subdistrict and community levels prior to campaign. One form was used by health workers at the community level; after session completion, vaccinators sent the form to the upazila level. The second form was a compiled report form maintained by supervisors. 	<ul style="list-style-type: none"> - Daily reporting. Daily written reports were sent to subdistrict offices after completion of each vaccination session. To report to the national level, however, information was updated daily through phone and email communication after the sessions. Written reports of subdistrict vaccination sessions were largely not sent by the district to the national level until completion of the campaign, although some districts sent the written report every day through courier services or by fax to the EPI HQ. - Data quality. Ensuring data quality was not observed in all the sessions; in many cases, first line supervisors were not focused on the quality of the tally sheets and other MIS forms as they were being filled out by vaccinators. However, available health workers were able to improvise forms in a way that maintained effective reporting.
<p>Successful implementation of MR campaign</p>	
<ul style="list-style-type: none"> - Broad support across stakeholders. There was a strong political commitment to the Campaign (national level KII). EPI service providers expressed widespread satisfaction; more than 99% of respondents in the original four survey areas reported being “satisfied” or “very satisfied” with the MR campaign. The majority of caregivers also expressed belief in the utility of the campaign, with less than 1% believing it had no benefit (Annex 6, Table DD). - MR coverage. According to the post-campaign survey, 90% of all children were 	<ul style="list-style-type: none"> - Some inequities in coverage. Although overall coverage was relatively high, 10% of children were not vaccinated (Annex 6, Table EE). In 36% to 37% of cases (depending on age group), caregivers cited fears of side effects as the reason. In 43% to 54% of cases, the child was ill (Table 10). In all age groups, there was no difference in coverage. Children who did not attend school, children of uneducated caregivers, children whose families did not own land, and children who did not live in city corporations had lower rates of coverage (Annex 6, Table W).

<p>vaccinated with MR. Coverage ranged from 82% in Sylhet division to 94% in Rangpur division. Fifty nine percent of children received the MR vaccine in educational institutions and 31% received the vaccine in routine EPI centers (Annex 6, Table EE). The majority of service providers generally perceived the campaign to be “very successful” with regard to giving MR vaccine to children (77% to 100%) and keeping adverse events to a minimum (77% to 100%) (Annex 6, Table M).</p> <ul style="list-style-type: none"> - Positive impacts on routine EPI. The MR campaign had some positive impacts on EPI: improved communication; procurement of additional supplies; improved healthcare worker confidence and motivation; and reduced fear of vaccination in the community (KII). - In the exit surveys, only one (0.2%) caregiver was unable to obtain a necessary vaccination for their child. - Adverse events. Some adverse events occurred, but very few considering the likelihood of adverse events in this type of campaign with such a large target population (Annex 6, Table J). 	<ul style="list-style-type: none"> - Some negative impacts on routine EPI. There were some negative impacts on monitoring activities of routine EPI, including greater demands on health workers’ time, and in some cases failure to fulfill routine vaccination programs.
<p>Timely and appropriate adjustments according to information</p>	
<ul style="list-style-type: none"> - Rescheduling of the MR campaign. Due to political unrest and other factors, the campaign had to be rescheduled; this was done in a prompt and efficient manner, and took into consideration seasonality, school exam schedule, challenges of campaign implementation in remote areas, and status of vaccine procurement. - Adjustment for postponement and higher than expected demand. Demand for the MR vaccine was higher than expected because the campaign was postponed. Authorities adjusted target numbers with the support of the routine EPI registers. They also dealt with higher demand by streamlining processes (combining sessions to reduce travel time, planning, and duplication of effort) and, when necessary, receiving additional vaccines from buffer stock (Annex 6, Tables E and F). 	<ul style="list-style-type: none"> - Increased workload. Health workers reported time constraints for revising and reviewing registration, and consequently did not have enough time to visit all the households in their catchment areas; instead, they revised the target population after reviewing the child registration book, where age of children is recorded. They had to spend extra time for this task while continuing to manage routine EPI activities such as domiciliary visits and route EPI sessions (community level KII). - Stock-outs. While most of the 22 stock-outs that occurred during the 144 facility observations were swiftly addressed by calling for and receiving backup buffer stock, in five cases this was not done and the campaign was stopped before all children were vaccinated. In most of those cases

- **Timely approval of budget.** The entire Gavi MR campaign budget was above the amount that the Steering Committee, headed by the Health Minister, could approve independently; this additional approval process would have delayed the launch of the campaign. In response, the Health Minister incorporated some essential line items within the approved operational plan budget through intersectoral adjustment to reduce the total budgetary requirement for the MR campaign to an amount the steering committee could approve independently, therein facilitating the timely approval of the budget and implementation of the Campaign.
- **Increased cost.** Scarcity of transport caused increases in costs for subdistrict level managers conducting monitoring. Subnational level implementers spent their own money to hire private transport to transport vaccines, upon assurance of reimbursement from the central authority (*subnational-level KII*).
- (17/22), a supervisor was not present at the campaign (Annex 6, Tables E, F, and G).
- **Communication challenges.** Subnational KII revealed gaps in communication between vaccinators and Heads of educational institutes. Some educational institutes heads changed their decision on holding vaccination session at the latest hour, sometimes even on the on the day of session, but this was dealt with by making adjustments to the previous microplan (*subnational-level KII*).

Analysis of major challenges and successes

The primary objectives of the campaign evaluation are to assess the impact of the MR campaign on reducing susceptibility to measles and rubella and to assess the impact of the campaign on routine immunization systems. In the remainder of this section, we describe the key findings of the evaluation including those linked to the two main objects: the impact of the MR campaign on vaccine coverage and disease susceptibility and the impact of the MR campaign on routine EPI system. We then present an in-depth analysis of two key challenges and responses to these challenges associated with the implementation of the MR campaign.

Finding 1

Bangladesh achieved high awareness of the MR campaign among the population and, subsequently, achieve high coverage of the MR vaccine among the target age group. Differences in coverage were observed, with coverage lower in traditionally lower performing areas, among children with caregivers with no education, and children less than five years of age. High coverage led to large reductions in susceptibility to rubella in the target population. Measles susceptibility was already low prior to the campaign, reflecting historically high sustained routine coverage of measles vaccination and previous measles vaccine campaigns.

Measles and rubella antibody prevalence

Results of the DBS-based analysis of measles and rubella antibodies indicates that the prevalence of measles antibodies in the target population was universal in both the pre-and-post-campaign survey.

This reflects a combination of high routine measles vaccine coverage, previous measles vaccine campaigns, and exposure to disease.

The pre-campaign prevalence of rubella antibodies was substantially lower than that of measles antibodies. As noted above, rubella-containing vaccine was introduced into the Bangladeshi routine EPI in late 2012 (as part of the combined MR vaccine); this was the first mass campaign of a rubella-containing vaccine. This was reflected in the pre-campaign results for rubella antibody prevalence (Figure 12) with pre-campaign rubella antibody prevalence increasing with age (Figure 13). Overall prevalence of rubella antibodies was 58% in the pre-campaign survey. These findings are consistent with past studies in Bangladesh.¹⁵ The age gradient reflects longer disease exposure periods for older children; pre-campaign rubella antibody prevalence in younger children will also reflect provision of MR vaccine through routine EPI beginning in 2012.

Figure 12: Changes in rubella antibody prevalence between the pre-and-post campaign surveys in selected districts by age group

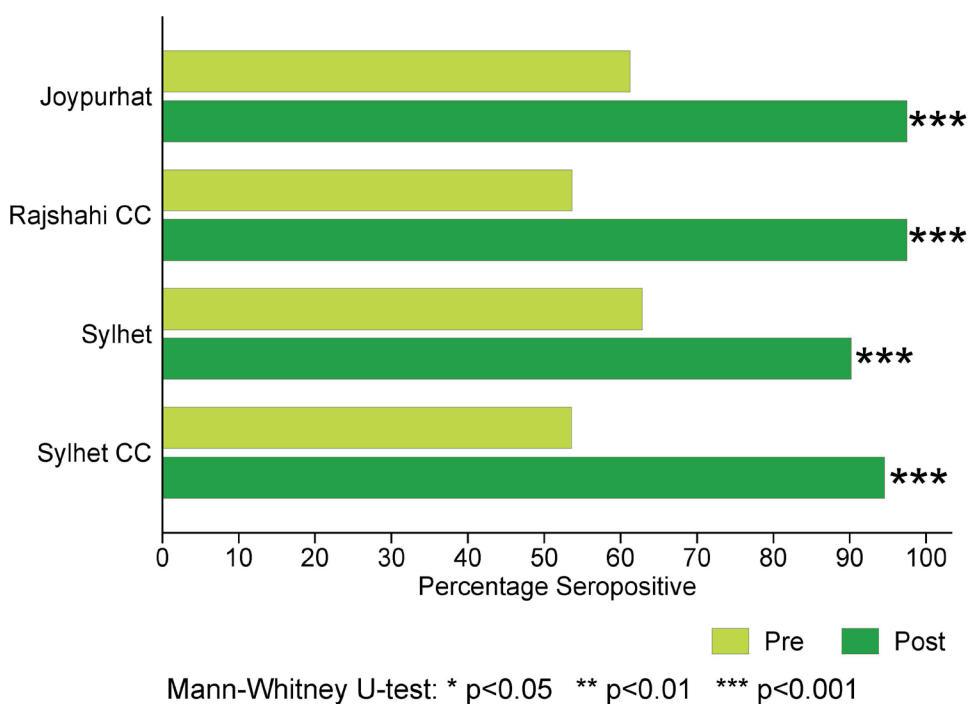
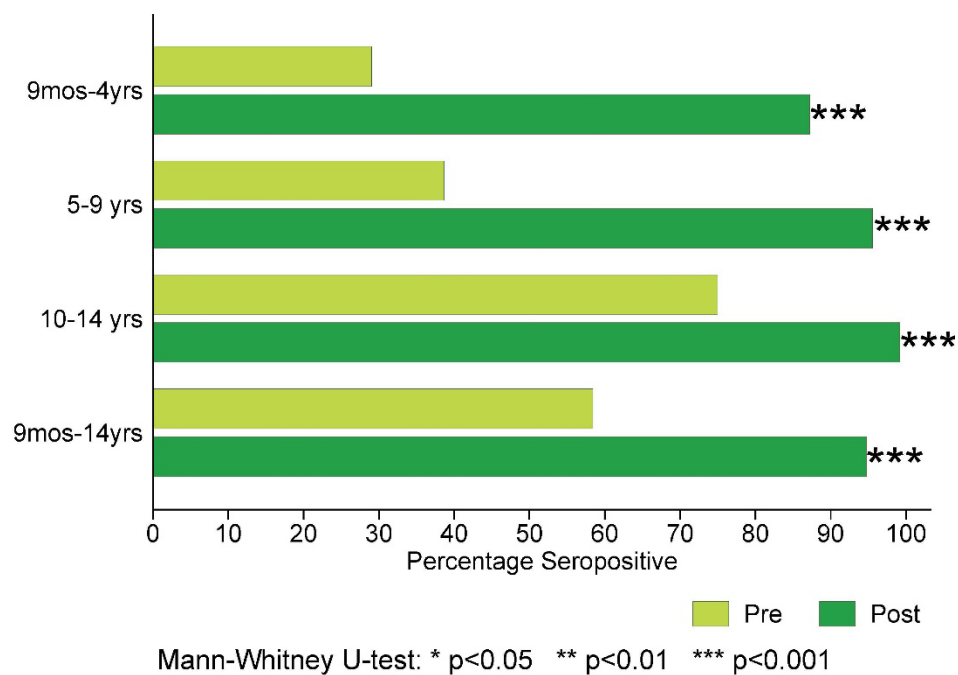
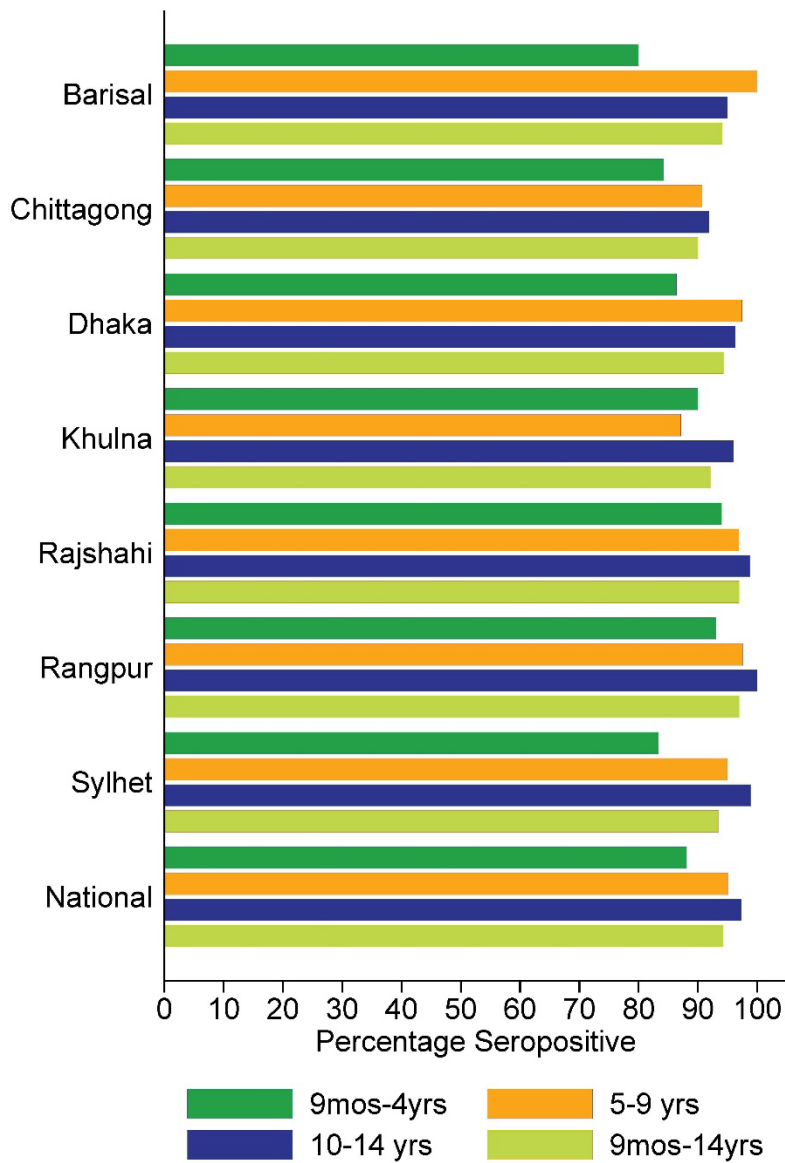


Figure 13: Changes in rubella antibody prevalence between the pre-and-post campaign surveys in selected districts by age



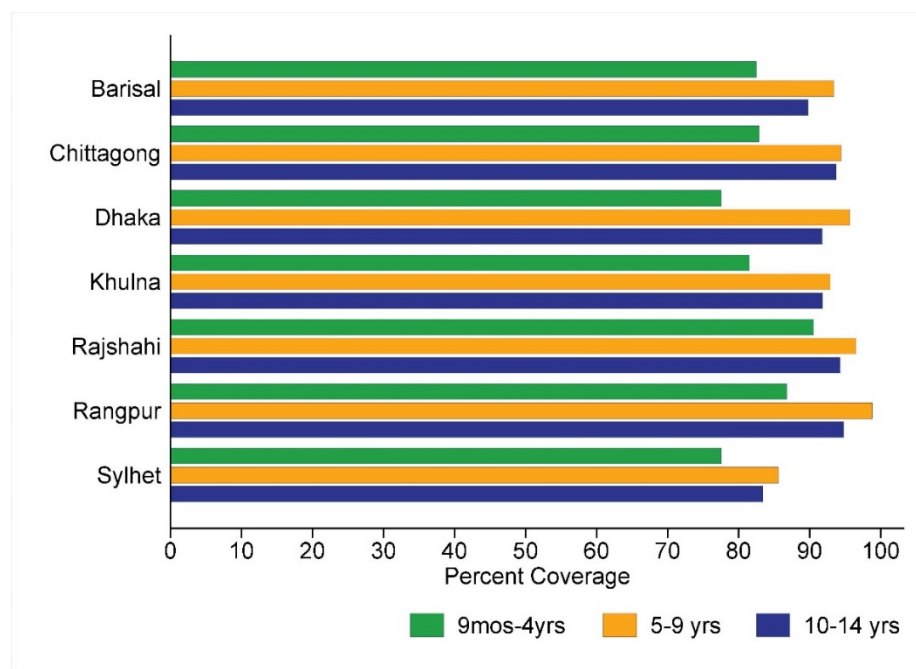
Rubella antibody prevalence increased substantially and significantly between the pre- and post-campaign surveys (Figure 12 and Figure 13). The presence of rubella antibodies in the pre-campaign survey is the result of two factors: (i) exposure to the virus, resulting in disease-induced antibodies,¹⁵; and (ii) the public provision of MR vaccine through routine EPI (beginning in 2012) and non-public provision, resulting in vaccine-induced antibodies. At the national level, post-campaign rubella antibody prevalence was 93% and was broadly similar across divisions (Figure 14), although there was variation by individual-level characteristics (Annex Table Q). The age gradient observable in Figure 14 is a function of greater disease exposure among older children, but is also likely due to high MR vaccine coverage as a result of the campaign. The conclusion that the MR campaign primarily led to increases in rubella antibody prevalence is further supported by a comparison of rubella antibody prevalence among those who received the MR vaccine as part of the campaign (96%) compared to those that did not (58.5%; Annex Table Q).

Figure 14: Rubella antibody prevalence by division, based on the post-campaign survey



MR Coverage

MR coverage, defined as recall of having received MR vaccination during the campaign, was 90%. Although overall coverage was high, there were some important differences to highlight by geography, gender and socioeconomic status. Coverage varied by division: Rajshahi had 94.0% coverage while Sylhet had only 82% (Figure 15).

Figure 15: Measles-rubella vaccine coverage by division and age

There were some notable differences in the coverage of the MR vaccine by age and socioeconomic status. Annex 6, Table R provides detailed results of these differences. We highlight the key differences in the main body of the report. Within every division, school-aged children five to nine years old had the highest coverage (Figure 15) and compared to children under the age of five, these children had a 15% increase in coverage (unadjusted risk ratio [RR] 1.15, 95% confidence interval [CI]: 1.11-1.21) (Annex 6, Table S). In multivariable analyses, children aged 5 to 9 and 10-14 had an 11% (adjusted RR=1.11, 95% CI: 1.04-1.18) and 83% (adjusted RR=1.83, 95% CI: 1.34-2.49) increase in coverage, respectively (Annex 6, Tables Y and Z).

In addition, children who attended school were 18% (unadjusted RR 1.18, 95% CI: 1.13-1.23) more likely to be vaccinated, compared to those who did not attend school (Annex 6, Table S). These results suggest that school-based campaign delivery was more successful than the EPI center based delivery. As Bangladesh prepares for other potential school-based vaccine delivery programs, such as HPV vaccine, lessons from the MR campaign could be applied to achieve similarly high coverage.

There was gender equity among children of all ages (Annex 6, Tables S-V). In terms of socioeconomic differences, children of caregivers with a secondary or higher education had a 7% (unadjusted RR 1.07, 95% CI: 1.02-1.12) increase in coverage compared to children of uneducated caregivers (Annex 6, Table S). Land ownership was also positively associated with vaccine coverage (unadjusted RR 1.07, 95% CI: 1.03-1.11) (Annex 6, Table S). For all ages combined, multivariate analyses revealed that child registration, secondary education of the child's caretaker, land ownership, and living in a city corporation were all positively associated with increased coverage (Annex 6, Table W).

The campaign's high coverage was achieved despite relatively low levels of personal communication with caregivers through the registration process, which was reported to be less than or equal to 20% in across all age groups in the post-campaign survey (Annex 6, Table P). Despite being uncommon, child registration was significantly associated with higher MR coverage (adjusted RR 1.08, 95% CI: 1.01-1.16)

(Annex 6, Table X). Child registration is also the only correlate that was significantly associated with coverage for each age stratum in both univariable and multivariable analyses (Annex 6, Tables S-Z). This indicates that expanded registration in subsequent campaigns may be an important approach for increasing vaccination coverage

Awareness of the campaign and reasons for not vaccinating

In our post-campaign survey, we found that nearly 13% of primary caregivers of unvaccinated children did not know about the campaign. This ranged from 12.7% among caregivers of children nine months to four years to 14.1% among caregivers of children ages five to nine years (Table 10). In every age group, more than a third of caregivers of unvaccinated children cited fear of side effects or the child's sickness at the time of vaccination as a reason for non-vaccination. Overall, 16% of the respondents cited other non-specified reasons (Table 10). Only a small minority of caregivers reported that their child did not receive the MR campaign vaccine due to supply side factors: seven (1.0%) individuals tried to obtain a vaccination but were denied care; five (0.9%) stated that the vaccine was not available; one (less than 0.4%) found the facility to be closed; and one (less than 0.4%) was referred elsewhere. In a survey of 574 individuals exiting EPI centers during the campaign, one (less than 0.2%) caretaker reported desiring the MR vaccine for their child, but was told it was unavailable.

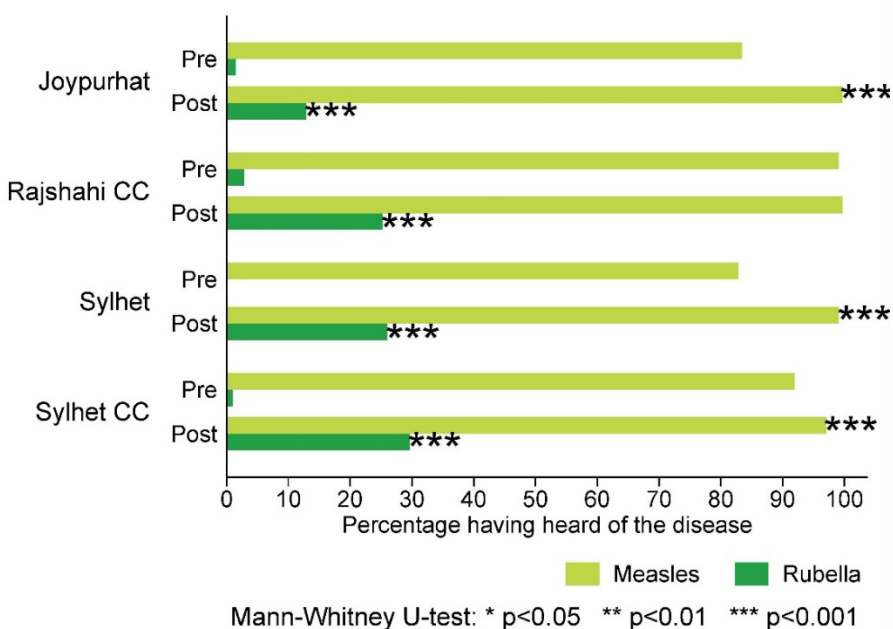
Table 10: Percentage distribution of reasons for not vaccinating children under the MR campaign by administrative divisions

Reasons for not vaccinating	Total (n=492)	Barisal (n=47)	Chittagong (n=37)	Dhaka (n=43)	Khulna (n=39)	Rajshahi (n=57)	Rangpur (n=29)	Sylhet (n=240)
<i>Nine months to four years</i>								
Unaware of campaign	12.7	11.1	27.8	4.2	0.0	17.4	16.7	21.3
Fear of side effects	35.8	50.0	46.2	34.8	23.5	36.8	28.6	32.9
Child was sick	42.7	31.3	15.4	65.2	17.6	26.3	42.9	34.3
Other	16.3	12.5	38.5	0.0	41.2	36.8	7.1	18.6
n	207	18	18	24	17	23	18	89
<i>Five to nine years</i>								
Unaware of campaign	14.1	0.0	0.0	28.6	11.1	0.0	0.0	24.6
Fear of side effects	35.9	41.7	10.0	40.0	62.5	61.5	0.0	39.6
Child was sick	54.4	50.0	80.0	60.0	37.5	15.4	100.0	37.5
Other	6.7	8.3	10.0	0.0	0.0	15.4	0.0	10.4
n	118	12	10	7	9	13	2	65
<i>10 to 14 years</i>								
Unaware of campaign	13.9	0.0	22.2	8.3	15.4	0.0	22.2	26.7
Fear of side effects	37.3	35.3	42.9	30.0	45.5	42.9	28.6	42.9
Child was sick	46.5	47.1	57.1	70.0	36.4	14.3	0.0	31.7
Other	10.6	23.5	0.0	0.0	18.2	23.8	28.6	14.3
n	167	17	9	12	13	21	9	86

Knowledge of measles and rubella

In the post-campaign survey, nearly 99% of respondents had heard of measles, with relatively little variation between divisions (Annex 6, Table AA). However, only 92.3% thought measles could be prevented, with percentages as low as 85.4% in some divisions. In contrast to measles, less than one in five respondents in the post-campaign survey had heard of rubella and only one-tenth thought it could be prevented, with substantial variation between divisions. This might be due to the fact that, unlike measles, there is no local name for rubella and the MR vaccine has only been incorporated into routine EPI for two years. It is important to note though that the awareness of rubella improved notably from the pre-campaign survey (Figure 16). Among those who said these diseases could be prevented, nearly 97% cited measles or MR vaccination for the prevention of measles and approximately 97% cited MR vaccination for the prevention of rubella.

Figure 16: Changes in awareness of measles and rubella



Recommendations

1. **Following an overall successful MR campaign, the Bangladesh EPI program and country-level partners should consider targeted efforts that focus on low coverage areas and groups, as identified by surveillance and coverage data, and shift attention to maintaining high routine MR vaccine coverage.**

By implementing the MR campaign and achieving high MR vaccine coverage, the EPI program and partners achieved high-levels of protection against rubella as measured by the change in rubella antibody prevalence between the pre-and-post-campaign surveys. Measles antibody prevalence was high in both the pre-campaign and post-campaign surveys. Although high overall levels of protection for both measles and rubella are present, lower vaccine coverage and rubella antibody prevalence were observed for some groups. For example, MR vaccine coverage was lower in traditionally lower performing divisions like Sylhet and was lower among preschool aged children and children of lower

socioeconomic status. Although the initial “catch-up” campaign was successful in terms of overall coverage the government and partners may consider targeted efforts (“mop-up”) approaches to vaccinate these lower coverage populations.¹⁶ This should be guided by high-quality surveillance data and/or other population-based survey data already established in the country.

In parallel, the focus should be on maintaining (“keep-up”) high routine MR vaccine coverage.¹⁷ For both “mop-up” and “keep-up” activities, interventions could consider a number of approaches to reach low coverage populations. These include the use of interpersonal communication (door-to-door visits by community-based health workers), which was used in the MR campaign and was shown to increase the likelihood of a child being vaccinated. Strategies implemented elsewhere, like village meetings communicating the costs and benefits of new vaccines, as well as targeted information campaigns, have been shown to improve vaccine uptake in low-performing communities in Pakistan.¹⁸ Expanded demand-side activities, such as financial and non-financial incentives, might also be particularly effective in these areas.¹⁹

2. The Bangladesh EPI program and country-level partners should focus future social mobilization and demand generation activities on increasing awareness and understanding of rubella.

Awareness of measles in the population was high based on the post-campaign survey. However, though the campaign led to increased knowledge of rubella, the overall level of awareness was comparatively lower. This is not surprising, given that multiple campaigns were implemented for measles in Bangladesh and that the vaccine was delivered as part of routine EPI for many years. In contrast, the MR campaign was the first mass campaign of a rubella-containing vaccine and the MR vaccine was only recently introduced into the routine EPI system. Enhancing population awareness of rubella is an important mechanism for increasing understanding of the rationale of the MR vaccine over traditional measles vaccine. We recommend that social mobilization efforts focus on developing a better population-level understanding of rubella.

Robustness of Finding

Finding	Ranking	Robustness Criteria
Bangladesh achieved high awareness of the MR campaign among the population and, subsequently, achieve high coverage of the MR vaccine among the target age group. Differences in coverage were observed, with coverage lower in traditionally lower performing areas, among children with caregivers with no education, and children less than five years of age. High coverage led to large reductions in susceptibility to rubella in the target population. Measles susceptibility was already low prior to the campaign, reflecting historically high sustained routine coverage of measles vaccination and previous measles vaccine campaigns.	A	This finding is supported by strong data triangulation from multiple quantitative methods (campaign observation, exit interviews, population surveys, measles and rubella antibody prevalence study).

Finding 2

The MR campaign had a range of positive effects on the routine immunization system, ranging from strengthened delivery systems to increased demand for vaccination. Some negative effects were also noted, including reduced monitoring and supervision of routine EPI due to campaign demands on health worker time. There was also some missed opportunities for catch-up of other vaccines.

As part of the evaluation of the MR campaign, we identified a number of effects of the campaign that are likely to have impacts on the routine immunization system. These are discussed in further detail below.

Increased public awareness and acceptance

During preparation for MR campaign, the government of Bangladesh was concerned that persistent fears among the population about adverse events and child death from a Vitamin A campaign in March 2013 would impact on demand for MR vaccine. Our findings suggest, however, that the MR campaign helped to reshape perceptions. One rural-level respondent stated:

Our routine EPI coverage became low after the rumor of Vitamin A Plus Campaign. The situation changed in the community after the MR campaign. Specifically, when people came to the MR campaign sessions, they gained a better understanding and reduced their misconceptions. They realized that these vaccines have been introduced for their welfare. We also mentioned to the guardians that Vitamin A Plus Campaign's adverse news, which were broadcasted were nothing but rumors. (Subnational-level KII)

Along these lines, strong relations between the MOHFW and the media enabled effective messaging around MR campaign-related AEFIs.

For immunization, when you are handling a campaign, usually it is done over three weeks, almost a quarter/third of population. So the risk gets magnified and known immediately because it is not routine. In this instance there were a few deaths, and this was reported in Bangladesh media, but reported in a very responsible manner, without sensationalizing it. It was not my firsthand experience, but I heard back, that MOH has a good relationship that resulted in this being reported responsibly. (Global-level KII)

Overall, the campaign increased public awareness of the intended effects of the vaccine and acceptance during both the campaign and routine EPI sessions. This finding is consistent with proposed Supplemental Immunization Activities (SIA) associated activities to strengthen routine immunization²⁰ and consistent with findings from previous campaigns in Bangladesh and elsewhere about the benefit of campaigns in increasing community awareness.²¹ The well-planned advocacy strategies from the national-level to the upazila-level, effective social mobilization process through mobile miking, SMS from mobile telephone companies, television commercials, and use of IEC materials helped in increasing mass awareness. Post-campaign survey data reveal that the majority of mothers heard of the campaign through word of mouth (Annex 6, Table M), suggesting strong social acceptance of the campaign. The Lion's Club was one organization that was very visible in social mobilization efforts.

There were thousands of Lions members mobilized for campaign, they were doing road shows in the lead up to the campaign, there were quite a few events that Lions in country had organized in support of the MR campaign. We obviously can't tell if that was

the contributing factor causing success of campaign, but shows that many partners can mobilize for whatever the country needs. (Global-level KII)

Improved provider-caregiver communication

This campaign has improved the communication between service providers and caregivers during the preparation phase of the campaign as a result of the door-to-door registration process. This door-to-door registration process increased provider-caregiver communication, and has the potential to improve communication for routine EPI since the providers had to visit every households to provide the campaign messages to the caregivers of the targeted children in addition to their routine visits at least once targeting the initial launching schedule on November 2, 2013. As noted earlier, revised registration levels were relatively low for the MR campaign.

Improved logistics

During the MR campaign, many logistics (e.g., vaccine carriers, ice packs, ice lining refrigerators, deep freezers, and vehicles) have been either repaired newly purchased. Although most of these logistics were very costly, they were critical for preserving the quality of the vaccines. These logistics will also be available to the routine EPI program. One subnational-level service provider stated that:

I had to use the campaign freezer for storing other vaccines since it required at least ten days to repair and service of one of my freezers. So I had to use that freezer to continue my routine activities. (Subnational-level KII)

These findings are consistent with previous measles campaigns in Bangladesh and other countries.²¹

Strengthened intersectoral coordination

In order to conduct such a large nationwide program, proper coordination and integration at different levels and across sectors was required. These lessons learned and experience can be incorporated in the EPI sector for future immunization campaigns and large scale health interventions.

It's true that the field workers (Health Assistant) post is vacant. Because of these vacancies, a huge additional workforce was needed for the MR campaign. This was met by using staff from Health and Family Planning departments under MOHFW, such as, Health Assistants, FWA, AHI, HI, FPI, SACMO, Medical Assistants, FWV, and Sanitary inspectors. Therefore, though the health workers post was vacant, they meet the vacant post by utilizing other workforces. (National-level KII)

Demand on health worker time and implications on routine activities

The MR campaign was designed to minimize interference of routine EPI activities by scheduling campaign activities for five days of the week with routine EPI activities for two days of the week. While we did not identify reports of routine EPI sessions cancellations due to campaign activities in contrast to experiences in other countries,²² it is important to note that this resulted in a significant workload for EPI service providers as evidenced by the EPI provider survey conducted. This mirrors findings for past campaigns in Bangladesh as well as other countries.²¹ However, KIIs suggest that health workers were highly motivated to work extra hours. The heavy workload during the campaign weeks also resulted in

less supervision and monitoring of routine immunization because of the campaign demands on Assistant Health Inspectors.

Catch-up immunizations for MR vaccine recipients

Mass immunization campaigns offer an important opportunity to catch-up or provide booster doses for other antigens for children receiving the campaign vaccine.²⁰ The MR campaign was not explicitly designed to catch-up on other antigens. KIIs indicate that some health workers did use the opportunity for catch-up. However, some missed opportunities from the post-campaign survey remain; among children 9-35 months vaccinated with MR during the campaign, 1.3% lacked the third dose of pentavalent vaccine Table 11 with this number increasing to 4.2% among three to five-year-olds receiving the campaign vaccine. Bangladesh has high vaccination coverage, so this represents a relatively large fraction of, and absolute number of, unvaccinated children.

Table 11: Percentage of children not having completed three-dose pentavalent vaccination, among those who received MR vaccine through the campaign

	9 mo-35 months (n=434)	36-59 months (n=542)
Penta-3	1.3	4.2

Recommendations

- 1. Gavi and partners should ensure that appropriate technical guidance is provided to EPI programs in the design of campaigns so that positive impacts are maximized and negative impacts are minimized. This includes, but is not limited to, designing campaigns as an opportunity for provision of catch for other vaccines.**

A requirement of Gavi support for campaigns such as the MR campaign is that countries should describe in the application how “campaign-planning, implementation and/or follow up will strengthen routine immunization.” The guidelines also note examples of how campaign design can strengthen the routine EPI, ranging from broader demand generation to system strengthening activities like cold-chain improvements, training, and waste management. Based on global-level KIIs, the design of these campaigns in how they might impact routine EPI is left up to countries to decide. Guidance from partners exists on how this might be achieved;²⁰ ensuring that this is reflected in the design of campaigns will allow positive impacts to be maximized and negative impacts to be minimized. For example, while there were a range of positive impacts of the campaign on the routine EPI system, one area that we identified as a missed opportunity was the design of the campaign as a mechanism for catching up children on other incomplete vaccines. While the campaign was not designed as an opportunity for catch-up, some health workers did use the campaign as an opportunity to identify children who had incomplete vaccination schedules. At the same time, there were missed opportunities for catch-up of the third dose of pentavalent vaccine in the post-campaign survey (Table 11).

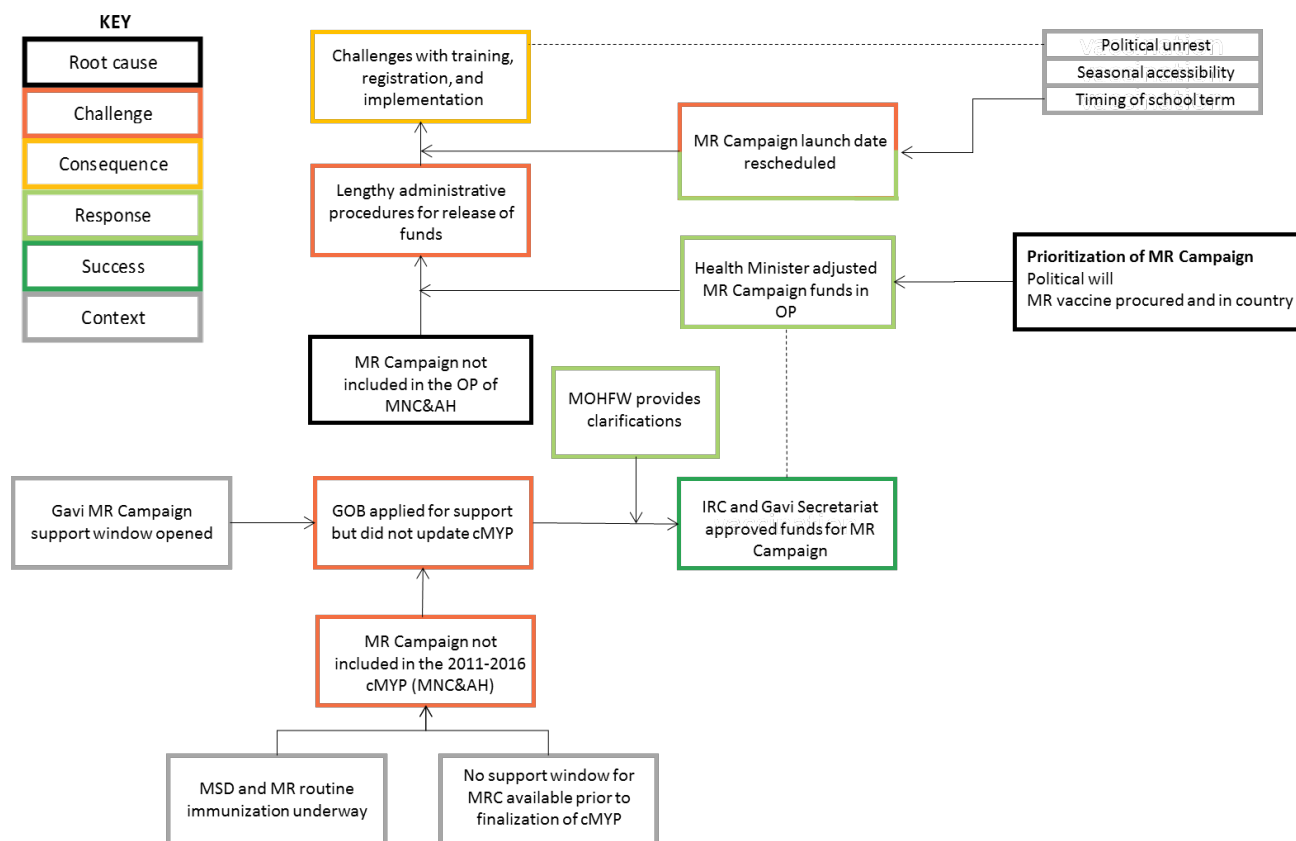
Robustness of Finding

Finding	Ranking	Robustness Criteria
The MR campaign had a range of positive effects on the routine immunization system, ranging from strengthened delivery systems to increased demand for vaccination. Some negative effects were also noted, including reduced monitoring and supervision of routine EPI due to campaign demands on health worker time. There was also some missed opportunities for catch-up of other vaccines.	A	This funding is supported by strong data triangulation from multiple quantitative and qualitative data sources

Finding 3

The MR campaign was not included under the operational plan (OP) of Maternal, Neonatal, Child and Adolescent Health (MNC&AH) as the plan was developed prior to the opening of the Gavi support window for the MR campaign. In the context of Bangladesh, no money can be allocated or spent for any other activities except the line items described in the endorsed OP. The subsequent lengthy administrative procedures required for the release of funds resulted in a delay in approval of the budget for preparatory activities and launch.

One of the key challenges noted from process evaluation was the delay in the approval of the MR campaign budget. Administrative delays, on the part of the government and Gavi, were observed in other studies of immunization policy in Bangladesh, but were not explored for root causes.²³ This delay created multiple downstream consequences pertaining to training, registration, and implementation activities (see also Finding 4). Figure 17 outlines a causal chain of factors and root causes. It also highlights responses by the country stakeholders that enabled MR campaign launch to proceed.

Figure 17: Root cause analysis for delays in approval of the budget for the MR campaign

The opening of Gavi’s window of support for the MR campaign in November 2011 provided a new opportunity for the GOB to tackle the measles and rubella disease burden and to build on existing immunization activities in country. However, the cMYP (2011-2016) of EPI program under the Operational Plan (OP) of Maternal, Neonatal, Child and Adolescent Health (MNC&AH) did not include the MR campaign because at the time the cMYP was finalized, no window of Gavi support was available for a MR campaign. Additionally, the cMYP already included government-funded MR routine immunization activities and Gavi-supported measles second dose (MSD).

After opening the Gavi MR campaign window, GOB submitted a revised application to Gavi on January 28, 2013 after an initial application was submitted in August 2012, as noted by a national-level KII. Gavi approved funds in April 2013, with the approval letter from Gavi noting the absence in the application of an updated cMYP costing tool to address the introduction of MR campaign, but highlighting satisfactory estimates of MR campaign cost and routine MR coverage. According to a global KII, the application was approved primarily on the basis of GOB’s prior experience with MR vaccine in routine immunization, GOB’s demonstrated satisfactory coverage rate (over 80%), as well as financial sustainability. However, final approval came after some rounds of communication between the country, IRC, and Gavi Secretariat to clarify open questions on the budget and implementation plan.

Their [GOB] first application was conditionally approved, meaning IRC felt at the time the country had not produced an introduction plan, whereas the country had already introduced [MR] into routine at the time... There was an agreement that, rather than

country going back and drafting an introduction plan post event, it didn't make sense for them to do it... When they [GOB] came back with clarifications, the response had to go back to the IRC again, and IRC said fine. There were still clarifications on budget, but they weren't major, so IRC left it to Gavi Secretariat to resolve remaining questions on the budget after the second, the conditional, IRC. (Global-level KII)

Following the disbursement of funds from Gavi, the MR campaign needed to be incorporated in a revised OP through updating the Program Implementation Plan (PIP) by the high level decision-making body called the Executive Committee of National Economic Council (ECNEC) as the MR campaign was not included in the OP of MNC&AH. This process would require various formalities. In the context of Bangladesh, no money can be allocated or spent for any other activities except the line items described in the endorsed operational plan. This resulted in a delay in approval of the budget for preparatory activities and launch. At this time, the MR vaccine had already been procured for the campaign and was in country, thus there was a priority to proceed with the launch, rather than postpone it to complete the formalities of revising the corresponding operational plan.

The Honorable Minister (MOHFW) was also motivated to implement MR campaign during his tenure, and used his authority on the steering committee to incorporate the most essential line items of the overall MR campaign budget through intersectoral adjustment of the MR campaign funds within the OP budget limits. A national-level key informant indicated the following:

We have submitted [the budget] to the ECNEC but they returned it back. Which meant that they have instructed us "submit it in this way, this is not it, there is no summary, delivery it to ERD, and it will go to Finance Ministry then to the Health Ministry. It must come through this system." MR campaign implementation would not have been possible in the next one year, if it went through this system, and the vaccines had already arrived. Therefore, it was decided by the Minister, who had power or capacity, because there is a committee in the Ministry, I do not remember exactly what but, it may be known as the Steering Committee meeting where the Minister can approve some amount of money for promotional plans, and through this method the funds were allocated. (National-level KII)

In parallel, the launch date was rescheduled to late January 2014. The timing of the new launch date required careful consideration of external factors, including political unrest in country, seasonal accessibility of vaccination sites, and timing of the school term in order to access the school-based target population. Stakeholder experience obtained from previous vaccine campaigns aided this process.

This RCA reveals that the decision not to revise the cMYP for MR campaign was not especially problematic, given Gavi's flexibility in approving funds based on country's evidence of ability to introduce MR into the routine immunization. However, delays in the approval process related to the submission of the budget to ECNEC were a key factor that led to the rescheduling of the launch. This step had not been included in the implementation plan. Given Gavi's official policy and the potential pitfalls of not complying with this policy, the question arises as to whether the application process could have benefitted from earlier communications between Gavi Secretariat, partners, and the GOB on operational and fiscal reporting requirements. It is also worth considering whether the bottleneck

created by submission of budget to ECNEC could have been anticipated by earlier planning around budgetary requirements. According to a global key informant:

They [GOB] had a couple of months' delay, which is not all that bad. Personally, I think they managed it pretty well. But they probably could have foreseen the limit on the budget, having to go to parliament and be approved. (Global-level KII)

These circumstances suggest a gap in communications between country officials and between the country and the Vaccine Alliance around accountability requirements as a precondition for the release of Gavi funds. Challenges with technical coordination have been observed by others studying immunization in Bangladesh.²⁴ Additional investigation with global- and national-level key informants will help to clarify this questions. We tentatively propose the following recommendation with that qualification in mind.

Recommendations

- 1. Country governments should initiate dialogue internally and with the Gavi Secretariat about country needs and administrative requirements for new support streams well in advance of the opening of the support window to enable timely updating of key operational documents (e.g., cMYP and operational plan).**

Robustness of Finding

Finding	Ranking	Robustness Criteria
The MR campaign was not included under the operational plan (OP) of Maternal, Neonatal, Child and Adolescent Health (MNC&AH) as the plan was developed prior to the opening of the Gavi support window for the MR campaign. In the context of Bangladesh, no money can be allocated or spent for any other activities except the line items described in the endorsed OP. The subsequent lengthy administrative procedures required for the release of funds resulted in a delay in approval of the budget for preparatory activities and launch.	C	Document review supports that non-inclusion of MR campaign in the PIP/OP delayed in MR budget approval. Other aspects of this finding were derived from limited KIIs.

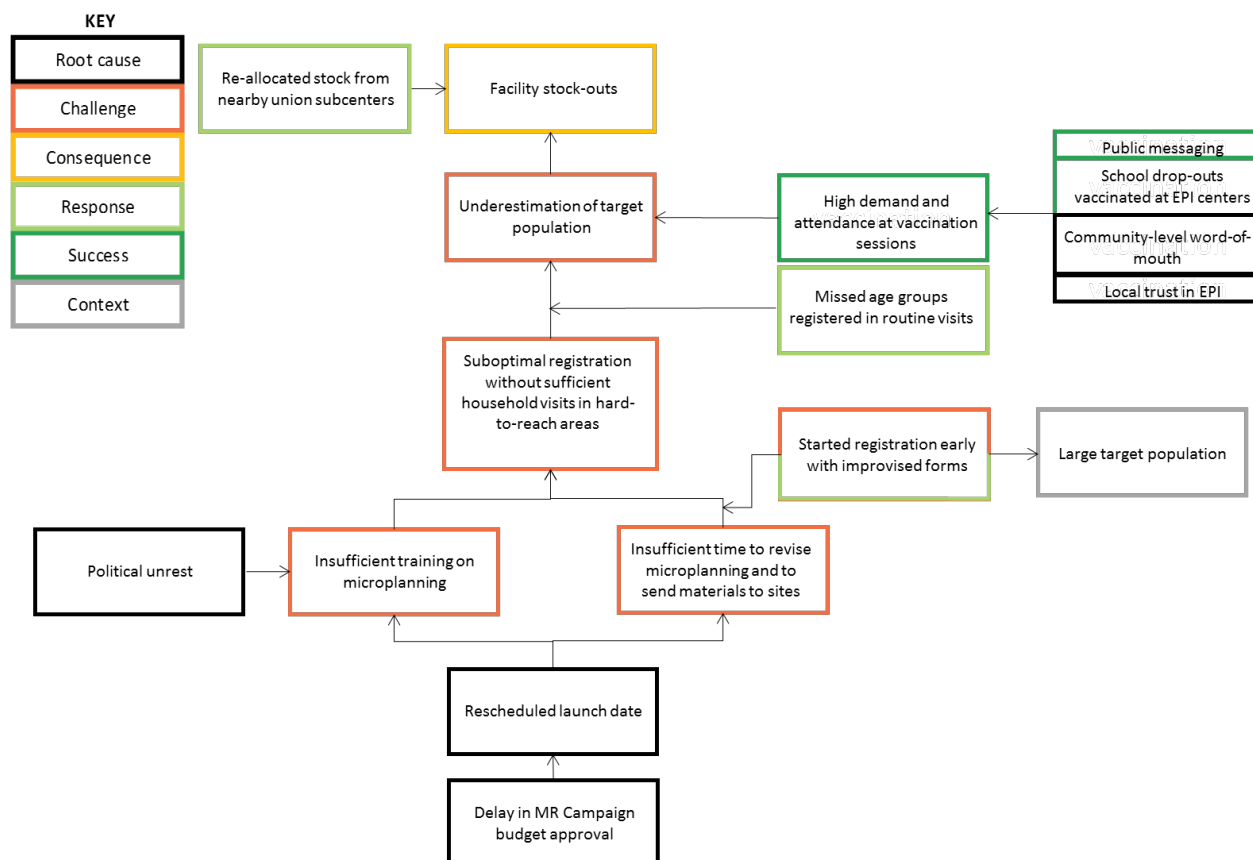
Finding 4

Some campaign delivery points experienced vaccine stock-outs caused by a number of factors. Suboptimal micro-planning and target population registration led to underestimation of the target population which converged with high vaccine demand, resulting from successful planning activities to result in stock-outs.

Another challenge encountered during the MR campaign pertained to vaccine stock-outs in about 15% of the school-based and facility based vaccination sites (Annex A, Tables E and F). The stock-outs were

successfully managed by reallocating buffer stock from union subcenters near the vaccine sites. However, the bottlenecks leading to the stock-outs involved a complex array of contributing factors which merit attention for future learning. Figure 18 illustrates three convergent causal pathways: suboptimal microplanning and registration; successful demand generation; and transportation and delivery challenges.

Figure 18: Root causes analysis for MR vaccine stock-outs



Bottlenecks around microplanning and registration stem from a number of root causes. Firstly, the delay in the MR campaign budget approval and subsequent rescheduling of the launch date (see Finding 3) along with political unrest (*hartals*) cut short training days. Health workers also described difficulties using registration forms and recommended having separate training activities that provided more focus on registration procedures.

Secondly, the rescheduled launch reduced the time available to revise campaign microplans and to distribute registration materials from central level to local vaccination sites. Registration forms only arrived at sites around 20 days prior to the rescheduled launch and were inadequate in number at some locations. Given the concerns about the unavailability of forms and the need to register a large target population in a short period of time, health workers began registration early using improvised forms crafted from blank paper in order to complete the registration on time. Data from the improvised forms were eventually checked and transferred to official forms. The initial registration started early and prior to the arrival of forms, so seven- to eight-month-old children were considered outside the MR campaign

age-range. When the campaign date was delayed, these children entered into the eligible age range. This rescheduling led to the missed registration of children seven to eight months of age. After microplans were updated, these missed children were subsequently registered during routine household visits.

Thirdly, in some locations, particularly in hard-to-reach areas, registration was carried about by referring to existing EPI registers and consulting with the heads of the local *baris* (conglomerations of households dominated by kinship ties), rather than through face-to-face visits with caregivers. This observation explains the low levels of registration seen in the post-campaign survey. Limited household contact, along with training limitations and the delays with microplanning, contributed to overall suboptimal microplanning and registration.

Another point to note is that there was a temporary shortfall in funds for training activities because of miscalculation in budgets. The deficit amount was reimbursed later, after receiving the actual requisition from those areas. National- and subnational-level KIIs confirmed that a large amount of unspent money was refunded/surrendered from the field to the EPI HQ against some activities, including training and supervision monitoring.

Demand generation

A number of factors positively contributed to achieving high demand for MR vaccine. EPI used public announcements like “mobile miking” in mosques and mobile phone messaging to spread encouraging messages about MR vaccination. These messages countered circulating rumors and fears about adverse reactions that had originated from an ongoing Vitamin A scare. High demand was also engendered by positive messages spread through community-level networks and by a preexisting strong trust in EPI among the general population. Also, in some locations, children who had dropped out of school and missed school-based vaccination came to EPI centers to receive the vaccine. High demand coupled with suboptimal registration led to underestimation of the target populations, ultimately resulting in insufficient stocks in some facilities.

Overall, this analysis indicates that multiple causal pathways related to microplanning and registration, positive demand generation, and vaccine delivery challenges converged to cause MR vaccine-stock outs in around 15% of delivery points. The stock outs themselves had only minor impact on the campaign activities because buffer stock was available to fill the gaps and the program and partners were able to respond to the various challenges along the way.

Recommendations

- 1. The MOHFW and country-level partners should draw on MR campaign lessons and continue to invest in maintaining and institutionalizing the strong capacity for contingency management that can be carried forward for future vaccine introductions.**

The analysis demonstrates how EPI and local actors, along with partner support, were able to absorb and respond to various challenges that included the rescheduling of the campaign, budget and training shortfalls, and delays in materials and supplies. These successes are also notable considering that the MR campaign was undertaken in the midst of substantial political unrest. It is clear from the MR campaign that the partnerships around the EPI program are very strong, and have demonstrated learning from previous experiences such as earlier measles campaigns. We recommend that the

government and partners work to solidify and institutionalize this capacity, ensuring consistent participation from partners and formalized procedures, roles, and responsibilities in the partnership in order to respond to challenges for future vaccine introductions.

2. The MOHFW and EPI program should explore methods to better incorporate perspectives of stakeholders from various levels of the health system into higher-level decision-making with the goals of strengthening alignment and effectively implementing activities.

While health workers demonstrated initiative in improvising registration forms to mitigate delays in receiving them from the central level, these observations suggest that the central level could benefit from planning more effectively around local needs and taking better account of local capacities. We recommend that the EPI program consider strategies to incorporate subnational experience into higher-level decision making and plans.

Robustness of Finding

Finding	Ranking	Robustness Criteria
Some campaign delivery points experienced vaccine stock-outs caused by a number of factors. Suboptimal micro-planning and target population registration led to underestimation of the target population which converged with high vaccine demand, resulting from successful planning activities to result in stock-outs.	A	Conclusion supported by multiple sources of evidence (data and feedback from KIIs, campaign observations and population surveys).

Health system strengthening

Summary of country progress

Bangladesh first received Health system strengthening (HSS) funds from Gavi for 2009-2013, with a total award of US\$1,881,438. The majority of these funds remained unspent, for reasons described below. The GOB then re-programmed HSS funds and was awarded additional funds for the second wave of HSS; the total amount of second phase funds is US\$8,309, 438 (second phase of US\$6,428,000 and US\$1,881,438 unspent money of first phase). The HSS activities have been expanded to 19 new districts; with this expansion a total of 32 low-performing districts will receive support from the Gavi HSS funds. On May 18, 2014, the GOB submitted an Expression of Interest (EOI) to Gavi. GOB is currently at the stage of application development and submission of new proposal on HSS by January 25, 2015.

Table 12 describes the GOB's progress on implementing the HSS award, organized by the milestones of the HSS Theory of Change. Selected key challenges and successes are highlighted as well. This table represent a preliminary retrospective analysis based primarily on document review.

To allow for future monitoring and evaluation of the HSS support stream in Bangladesh, we compiled results on vaccine coverage using the small area estimates described in the introduction and Annex 3 for Phase I, Phase II, and non-HSS districts in Bangladesh as shown for DPT3 coverage in Figure 19. This figure shows that the gap between Phase I, Phase II, and non-HSS districts appears to be somewhat

closing. This statement is simply descriptive, and with a short-follow-up period we caution against making statements about attribution, either positive or negative.

Figure 19: Estimated DPT3 coverage with 95% uncertainty in Phase I, Phase II HSS districts compared to non-HSS districts (first HSS grant)

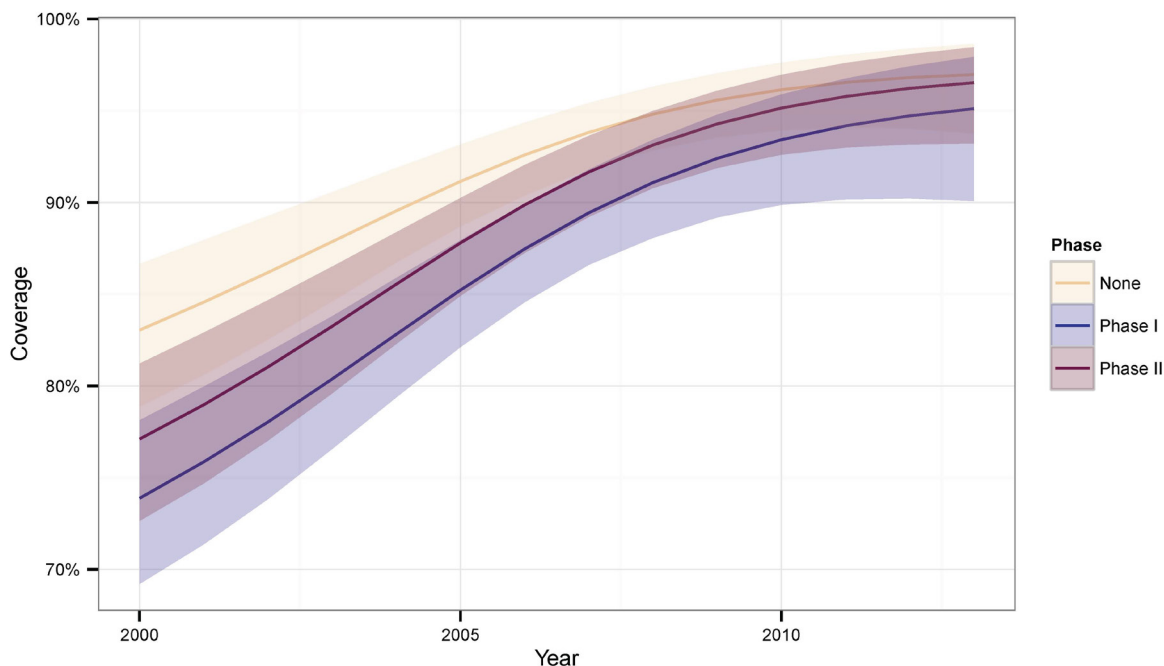


Table 12: Summary of country progress

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Critical bottlenecks to immunization coverage are identified	
<ul style="list-style-type: none"> - Bangladesh had reviewed existing activities and results in relation to the objectives, and identified inadequate functional capacities and infrastructure of community clinics to deliver safe and effective maternal and child health (MCH) and immunization services. - Rigorous procedures were followed that included subnational-level stakeholders to identify critical bottlenecks. - The process worked to ensure participation of stakeholders at all levels. 	<ul style="list-style-type: none"> - According to document review, the review process did not consider the WHO health system building blocks, as it was not mandatory part of application guideline. Not considering this in the guideline introduced the risk of inadequate analysis to comprehensively identify key bottlenecks.
Appropriate responses to address bottlenecks are identified/developed	
<ul style="list-style-type: none"> - Four key responses were elicited to address the identified critical bottlenecks: <ul style="list-style-type: none"> o In the revised program plan, the Health Assistant (HA) and Family Welfare 	<ul style="list-style-type: none"> - The level of stakeholder involvement at all levels was not documented in any documents reviewed.

<p>Assistant (FWA) vacant posts were to be filled, as this was critical to achieving high immunization coverage targets.</p> <ul style="list-style-type: none"> ○ Critical gaps in logistics, supervision management, and skills development were to be filled. ○ Critical gaps in equipment and physical infrastructure were to be filled. ○ High quality and appropriate MCH services were to have greater access through a combination of improved supply (e.g., MCH training) and increased demand. 	<ul style="list-style-type: none"> - There was limited evidence for devising responses, and limited demonstration of review of existing evidence, according to our document review.
<p>Adequate plans to facilitate implementation are developed</p>	
<ul style="list-style-type: none"> - A detailed plan was developed that included activities and timelines to reach each objective. - Policy makers and national-level managers from GOB and development partners actively participated. 	<ul style="list-style-type: none"> - Absence of log frame of HSS grant; although this was not a mandatory part of the first HSS grant. - Roles and responsibilities of key implementers were not specified in the HSS plan.
<p>Successful application to Gavi for funding</p>	
<ul style="list-style-type: none"> - GOB drafted application in mid-2007 and submitted it to Gavi in September 2008. - The Planning Wing of the MOHFW, and the Health Nutrition and Population (HNP) Forum were coordinated in submitting this application. - The Programme Development Committee (PDC) gave technical assistance on drafting the application. - Relevant stakeholders were actively involved in the process and timely need-based support was given by an external consultant from WHO. 	
<p>Sufficient amount of Gavi's HSS funding is secured in time</p>	
<ul style="list-style-type: none"> - Gavi HSS fund secured in 2009: US\$7,243,500 - Gavi HSS fund secured in 2014: US\$6,428,000 - Total: US\$13,671,500 	<ul style="list-style-type: none"> - Delayed response by the country in fulfilling Gavi's requirement for the audit report for the second phase of funds.
<p>Sufficient non-Gavi source of funds secured in time</p>	
<ul style="list-style-type: none"> - This is not applicable in the Bangladesh context, as there are no non-Gavi sources of funds. 	
<p>Plans for implementation are updated/reprogramming</p>	

<ul style="list-style-type: none"> - A committee was formed to reprogram the HSS activities on July 17, 2011. - Bangladesh applied for reprogramming of HSS grant on September 7, 2011. - In this reprogramming, an additional 19 districts were proposed to be covered in addition to the original 13 districts. - There was rigorous review of the needs and gaps of the program through active participation of the stakeholders. 	<ul style="list-style-type: none"> - There was delayed approval of financial guidelines by Gavi. - It is not clear if required procedures for reprogramming were followed adequately.
Sufficient funds are distributed to designated entities	
	<ul style="list-style-type: none"> - Document review details that first-phase HSS funds were not distributed on time.
The plans are implemented in a timely and comprehensive fashion	
<ul style="list-style-type: none"> - The first phase of HSS plans were implemented in a very limited way, with little or no recruitment, training, or community clinic infrastructure development. 	<ul style="list-style-type: none"> - HSS funds were not distributed on time or uniformly throughout the period as planned. - The phase one plan was not implemented on time. - There was a delay in recruitment and training. - There was insufficient reporting on monitoring.
Intermediate results are achieved	
<ul style="list-style-type: none"> - It was difficult to assess the achievement of intermediate results due to an incomplete Annual Progress Report (APR) submission by the country. 	<ul style="list-style-type: none"> - Limited quality of data in Annual Progress Report (APR) caused challenges in assessing intermediate results.
Immunization outcomes are achieved	
<ul style="list-style-type: none"> - The proposed data collection procedures was not extensive, and limited a time frame for assessing impact makes it difficult to assess immunization outcomes of the first wave of HSS. 	
Impact achieved	
<ul style="list-style-type: none"> - There was a delay in developing a mechanism to measure the immunization impact (i.e., annual coverage evaluation survey). 	

Analysis of major challenges and successes

Table 12 highlights progress, challenges, and responses associated with implementation of the first-phase of Gavi Health system strengthening support in Bangladesh. As the evaluation of HSS funds is

preliminary at the time of writing this report, the section below describes initial challenges and successes observed in the funding stream. Future reports will include further evaluation efforts and triangulation of findings.

Bangladesh initiated the first phase HSS application in mid-2007 and submitted the proposal to Gavi in March 2008. The proposal was developed in a participatory and inclusive process that was led by the planning wing of the MOHFW, development partners, NGOs, and subnational health officers. This process included a series of consultative meetings (six subnational and one national) organized by the MOHFW that were held between December 2007 and January 2008 to provide feedback on HSS. Participants in these meetings included representatives from district and upazila health offices, community-based NGOs and civil society organizations, and other ministries and development partners. The revised proposal was endorsed by the Health, Nutrition and Population (HNP) Forum, a high-level committee of MOHFW, on September 1, 2008.

The proposal designated HSS funds for addressing critical constraints on Health, Nutrition, and Population Sector Program (HNPS 1996-2011) targets. The overarching aim was to ensure that community clinics, the backbone of the new operational strategy for PHC, had the minimum functional capacities and infrastructure to deliver safe and effective maternal and child health and immunization services.

In 2009 Gavi disbursed the first tranche of HSS funds to the Planning Department of the MOHFW; the funds remained unspent for almost two years. While the FCE team is still exploring this issue, preliminary data have suggested various reasons for the delayed utilization of HSS funds. At the global level, Gavi Secretariat's implementation of the then-new Transparency and Accountability Policy (TAP) for the HSS window was beset by delays in finalizing the Financial Management Agreements (FMA) for all HSS-supported countries. At the country level there was limited awareness of the guidelines pertaining to the execution of Financial Management Requirements (FMR), and challenges related to staff turnover. In addition, the Planning Department, charged with HSS funds disbursement, was concerned about the changing national health strategy as a result of a newly elected national government, and the possible re-prioritization of the HSS grant, so funds were not disbursed to key implementation departments (i.e., the OP of SWPMM, MNC&AH, and CBHC) until after two years. Implementation activities around recruitment, health worker training, and infrastructure development for community clinics were not carried out; some of these consequences are described below, and further investigation and triangulation of these observations are needed to obtain a clearer understanding of the root causes of the delay in utilization of HSS funds.

Recruitment Process

As part of HSS activities, it was estimated that the total number vacant posts of Health-Assistants (HA) and Family Welfare Assistants (FWAs) was 489 in the initial 13 districts. As of February 2012, 451 Community Maternal and Child Health and Immunization (CMCH&I) workers were recruited to fill the vacancies. Numbers were also calculated for CMCH&I workers to fill vacant posts of HA and FWAs in all the 32 HSS supported districts. The first-phase HSS fund was to be disbursed to 32 districts for the recruitment of CMCH&I within a short period of time, since the time frame for the first phase was coming to an end. The recruited CMCH&I workers were not as skilled as HA and FWAs, since the HA and FWAs are very well-trained and have to perform activities other than immunization in their catchment areas. The CMCH&I workers were only employed to support the HSS activities and were paid by the Gavi

HSS fund. However, the regular turnover rate of community-level health workers, due to promotion, transfer, retirement and death, presented a significant challenge.

At the time of writing this report, the recruitment of various positions is still incomplete for 32 districts, despite the formation of two committees to recruit nine District Maternal Child Health and Immunization Officers (DMCH&IO), an assistant national coordinator, and a national level cold-chain engineer. The recruitment issue for the cold-chain engineer was also discussed in the first meeting of the committee for recruiting a cold-chain engineer, held August 14, 2014; this committee determined that there were not suitable candidates for the position and that the advertisement for the position would be re-published.

Infrastructural Development

One component that was successfully completed on time was the construction of cold stores. The Health Engineering Department (HED) was assigned the task of constructing 12 EPI cold stores in the first wave of HSS funds, which completed per the plan. The re-programmed HSS includes a provision for constructing 15 regional cold stores, construction of 100-bed hospitals at the district level, and all types of health facilities at subdistrict level. Construction will be monitored by various actors include LD, MNCAH, and MOHFW.

Unlike the construction of the 12 EPI cold stores, the construction of birthing rooms in community clinics is about ten months late, according to global KIIs. A total of 105 community clinics with birthing rooms were targeted for construction. As of March 2014, 104 of these were constructed; the schedule of construction activities was not maintained because of slow progress on the part of the Department of Public Health Engineering, which was responsible for the construction.

Monitoring activities

The first round of HSS support was supposed to provide vehicles for DMCH&IOs, to enable them to perform their monitoring activities. As this was not completed, ten of the DMCH&IOs were provided vehicles which were underutilized vehicles previously used by District Immunization Medical Officers (DIMOs) under the ISS funding award. Without disbursement of the first-round HSS funds for vehicles, minimal monitoring activities were performed, which resulted in an incomplete APR and with poor data quality.

Reprogramming of HSS

A second emerging theme regarding HSS in Bangladesh is the reprogramming of first phase HSS. Preliminary analysis suggests that the reprogramming of the first phase HSS funds was protracted due to limited familiarity with FMA guidelines at the central level, namely regarding submission of the External Audit Report. Factors related to political transition also slowed the process. Support from the Gavi Secretariat enabled the eventual submission of the External Audit Report.

Despite poor performance on first phase, as described above, Gavi advised GOB in 2011 to reprogram the HSS grant. A global stakeholder indicated that this decision was in line with donor push for the cash-based support mechanisms to better align with NVS.

Donors and Gates were pushing for more HSS focus on immunization across countries. So, if older grants [HSS] weren't started at this time, they had to*

proceed within new focus; those that were already started had to shift focus. The old HSS applications (in general) were still relevant but Gavi wanted Bangladesh to reprogram with focus on immunization. This caused delays too. (Global KII)

**"This time" also refers to when new Transparency and Accountability Policy was implemented (2009)*

Countries like Bangladesh with open grants that had yet to initiate activities were good candidates for reprogramming. GOB started the reprogramming the same year, but this process was bogged down considerably by a number of factors both at global- and country-level.

A global-level stakeholder indicated that the implementation of Gavi's Financial Management Assessment (FMA) process in 2009, under the new Transparency and Accountability Policy (TAP) had stalled HSS activities across many countries due to the lengthy time it was taking to process all the assessments, which was only completed in 2011.

The same stakeholder also described that reprogramming effort was hampered by the central-level factors in Bangladesh. These include the period of political transition, competing programmatic priorities and, most notably limited familiarity with the new FMA requirements. One example of this was that GOB was not aware of the external audit requirement:

Other lessons learned from HSS implementation were that capacity and bureaucracy were issues. And government did not understand all the new requirements, including the external audit requirement. They did not know they had to submit one. When we [Gavi] raised the issue, country seemed a bit surprised. They had to submit that in 2013 and it cleared in 2014. There are also capacity issues with limited bodies, not having financial management capacity and, let's say, issues with "attention span" of government regarding various programs. (Global KII)

Gavi personnel conducted a mission to Bangladesh to remind the country of FMA requirements. This process caused additional delays, but eventually GOB submitted the audit to Gavi in 2013 and received approval for reprogrammed funds in 2014. It is important to note that, at present, we have not obtained data from national-level stakeholders regarding the FMA bottleneck. However, three Programme Implementation Committee (PIC) meeting minutes reveal that initially a draft GAVI Financial Management Hand Book (FMHB) was prepared by a consultant of WHO. This FMHB was sent to the Gavi Secretariat by email for comments, and on December 5, 2011 (at the 11th PIC meeting), it was endorsed as final by the Senior Assistant Chief. She also said, "Now we need to finalize the FMHB and also need to send it to GAVI Alliance for approval." However, from 12th PIC meeting in February 2012, it was discussed again to provide feedback on the draft FMA handbook. Further investigation of this issue will help to clarify what appears to be a disconnect regarding the potential cause of the FMA bottleneck and whether partnership agreements under development will help to avoid such challenges in the future.

Upon exploring further, this issue reiterates the need for effective contingency planning at the central level in order to mitigate the operational challenges and uncertainties of political transition. It also reveals possible gaps in how well Gavi implemented the then new TAP policy in Bangladesh. While further evidence is needed, it stands to reason that effective and timely communication on this issue should have been a priority, given the push for GOB to reprogram around the same time. Further

investigation will be able to clarify the procedures around implementation of the FMA process, and how it can be improved in the current round of HSS application. The role of technical assistance from Vaccine Alliance partners on FMR will also be assessed.

Given the preliminary nature of the evaluation on this funding stream, no specific recommendations are given until further evidence can be obtained.

Other active funding streams

Pneumococcal conjugate vaccine

Summary of progress

The government of Bangladesh originally planned to introduce PCV10 into the routine EPI schedule in 2013, and submitted an application for the PCV10 VIG on May 12, 2011. However, the planned introduction was postponed due to the unavailability of vaccines in the global market. According to the 2014 Advance Market Commitment (AMC) annual report, both Bangladesh and Nigeria had to delay PCV introduction because of the global supply shortage. Smaller countries, like Mozambique, Uganda and Zambia, were able to introduce the vaccine in 2013.

PCV is currently scheduled for introduction in December of 2014; a summary of the country progress towards PCV introduction is presented in Table 13.

Table 13: Summary of country progress

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Timely and adequate plan & budget for PCV implementation and technical assistance	
<ul style="list-style-type: none"> - Application for PCV submitted in May 2011, with detailed implementation plan and budget developed. 	
Sufficient funding available in time	
<ul style="list-style-type: none"> - Gavi decision letter received on July 8, 2014, with approval for US\$3,233,500. 	<ul style="list-style-type: none"> - Updated total budget re-estimated at US\$3,597,077 was approved, where Gavi would provide US\$3,233,500, and UNICEF and WHO would fund the remaining US\$363,577.
Cold-chain and logistics system is prepared for PCV	
<ul style="list-style-type: none"> - Child EPI cards, vaccine tally sheets, and monthly reporting forms updated to include PCV. - An additional 30m³ of cold-chain space has been installed at the national level, with support from UNICEF. There was no additional space required at the subnational level. EPI HQ sent a clarification letter to Gavi in November, 2011, ensuring the additional storage capacity. - PCV fridge stickers (in Bangla) were printed and ready for after readiness certification. 	

Adequately skilled health workers are available	
- The national TOT was conducted in October of 2014; district-level training began in the third week of November 2014. Upazila-level trainings were targeted for completion by December 11, 2014.	- Some trainings did not occur on time, such as the training for District EPI superintendents, cold-chain technicians, EPI store keepers, medical technologist-EPI, and the national-level and consultative workshop with Pediatric Association/Professional Bodies. - Additionally, the national TOT was deferred from October 11-November 13, to October 30-December 18.
PCV readiness is confirmed	
- Readiness assessment was scheduled to occur by December 18, 2014.	
Sufficient volume of quality vaccine available	
- PCV was originally scheduled for introduction in 2013; global supply shortages led to postponement to 2014.	- PCV introduction was originally postponed until March of 2014; however global supply was slower than expected so PCV introduction was finally re-scheduled to December 2014.
Successful launch of PCV	
- PCV introduction was planned for December 2014.	

The global shortage of PCV significantly impacted Bangladesh's introduction plans. The global UNICEF Supply Division managed this situation, re-allocating PCV supply so that the upcoming introductions in the two large countries (Bangladesh and Nigeria) would not be hampered or further delayed.

The country readiness assessment is scheduled to occur by December 18, 2014. In preparation for this, the EPI program has taken the necessary steps to ensure vaccine shipment in December 2014. The national TOT was conducted in October of 2014; district-level training began in the third week of November 2014. Upazila-level trainings are targeted for completion by December 11, 2014, therein achieving the readiness requirement of trained health workers. Child EPI cards, vaccine tally sheets, and monthly reporting forms have been updated to include PCV. PCV stickers (in Bangla) have already been printed and stored at EPI HQ; they will be distributed after the completion of the trainings.

Document review has revealed that some trainings and events were not completed on time, such as the training for District EPI Superintendents, Cold-chain Technicians, EPI Store Keepers, Medical Technologist-EPI, and the national level and Consultative workshop with Pediatric Association/Professional Bodies. Additionally, the national TOT was deferred from October 11 to November 13, to October 30 to December 18. The FCE team is still exploring the reasons for this deferral.

Inactivated polio vaccine

Summary of progress

Bangladesh has been a WHO-certified polio-free country since 2006. The GOB plans to introduce Inactivated Polio Vaccine (IPV) in the routine EPI to mitigate the potential risk of re-emergence of type-2 polio, following the withdrawal of Sabin type-2 strains from oral polio vaccine (OPV). IPV introduction would conform to the Global Polio Eradication Endgame Strategic Plan 2013-2018 developed by World Health Assembly (WHA), which recommends at least one dose of IPV in the routine immunization program for those countries using only OPV.

In March 2014, the Government of Bangladesh submitted an application to Gavi, following the approval of the respective oversight committees. The proposed IPV target population is 17,340,025 children over a five year period (2014-2018). On 23 June 2014, the Scientific and Technical Subcommittee of National Committee for Immunization Practice (NCIP) recommended incorporating IPV at 14 weeks of the immunization schedule along with a third dose of OPV and Pentavalent vaccine, to be completed by the first quarter of 2015.

MOHFW received the approval letter for New Vaccine Support (NVS) for IPV from Gavi on June 30, 2014. Additionally, Gavi informed the MOHFW of its initial allocation of 10-dose vial presentation, given that there were not sufficient quantities of the single-dose presentation, preferred by GOB. According to the approval letter, Gavi expected to be in a position to provide the five-dose vial presentation as per the secondary preference of GOB, and expected to be in a position to accommodate this request, provided the vaccine achieved WHO pre-qualification of the vaccine in the third quarter of 2014.

The original plan was to roll out IPV simultaneously with PCV10 the fourth quarter of 2014. However, the IPV was not indicated in the current cMYP and operational plan. Thus, at 45th ICC meeting held on September 1, 2014, GOB decided to postpone the launch date to the first quarter of 2015 so that revision of the cMYP to include IPV can be completed.

In preparation for roll-out, GOB has ensured adequate cold-chain space at national, district and subdistrict levels after accommodating the vaccines currently use for the national immunization program.

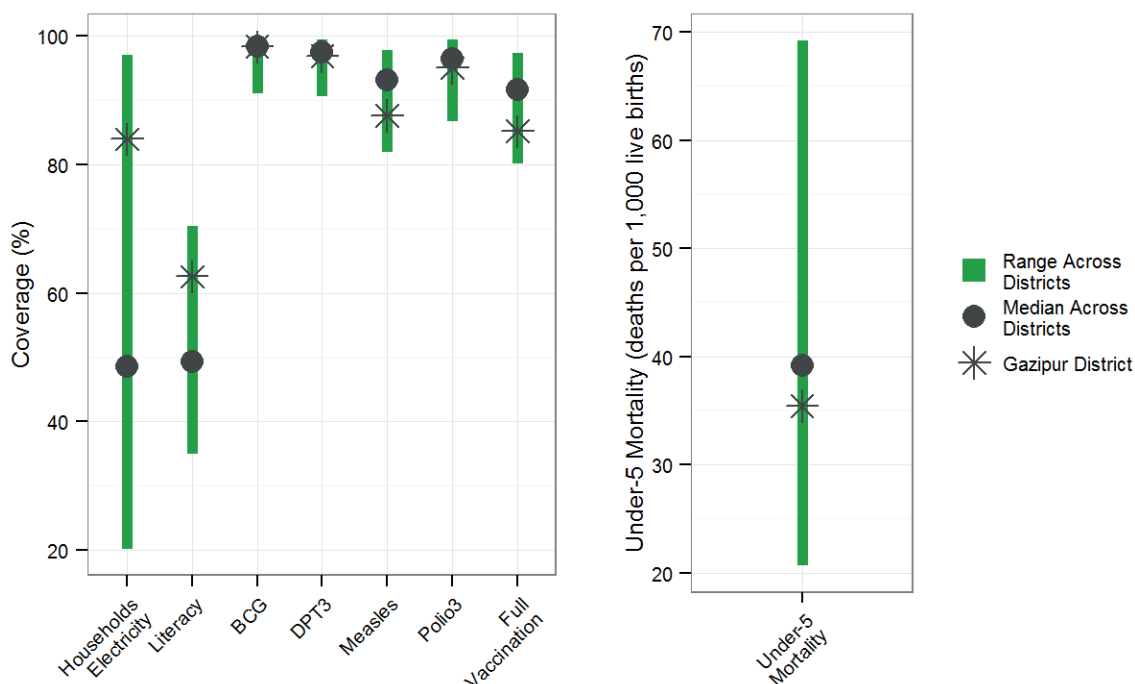
Human papillomavirus vaccine (HPV)

Summary of progress

The Government of Bangladesh submitted an Expression of Interest (EOI) to Gavi on May 18, 2014 for the introduction of HPV vaccine into routine EPI. To prepare for national introduction, GOB intends to carry out a demonstration project, to begin February 2015. Application for the demonstration project was submitted to Gavi on September 15, 2014. The Scientific and Technical Committee of NCIP had previously suggested the districts of Gazipur or Manikganj as potential demonstration sites. Gazipur was eventually selected, being a populous district close to the capital, Dhaka, where the EPI headquarters is situated. This will help to supervise or monitor the implementation activities of the demonstration project. Gazipur district achieves vaccination coverage comparable to other districts in Bangladesh. Gazipur district, however, has relatively high literacy levels and widespread access to electricity (Figure 20). Further investigation into the decision making process for district selection and whether there are parallels with Mozambique (p. 120) will be an area of focus for the FCE in 2015.

One additional area for process tracking for the Gavi FCE is the extent to which previous experience with a similar target population will help to guide the HPV vaccine demonstration project. Bangladesh has previously conducted measles vaccination campaigns from 2010, which targeted children nine months to 10-years-old. The recent MR campaign targeted children nine months to 15 years. These campaigns were conducted in both schools and communities.

Figure 20: Socioeconomic indicators, vaccine coverage and child mortality for Gazipur district compared to other districts



The target population estimated for vaccination in the HPV vaccine demonstration project is 30,000 with coverage target of 95%. The target group is a single-year cohort of females, 10-years of age. GOB selected the two-dose-per-vial bivalent HPV vaccine (Cervarix) for the demonstration project, considering limitations in cold-chain space. The one-dose-per-vial quadrivalent HPV vaccine (Gardasil) requires three-times the amount of space than the Bivalent preparation. However, the ICC agreed to switch from bivalent to quadrivalent HPV vaccine in near future, pending the expansion of cold-chain space.

Cross-stream analysis

The FCE in Bangladesh this year focused primarily on the implementation of the MR campaign. Although only preliminary process tracking of HSS and upcoming new vaccine introductions were also carried out, a number of cross-cutting themes are identified. In some cases, the noted issues rest more solidly on evidence from the MR campaign evaluation and suggest considerations to enable successful introductions of new vaccines and implementation of cash-based support moving forward.

Bottlenecks in the subnational disbursement and utilization of funds

Bottlenecks in central level bureaucracy in Bangladesh stalled the disbursement and utilization of funds for key immunization and system strengthening activities in both MR campaign and first phase HSS support streams. Absence of an updated program implementation plan (PIP) and of top-down budgeting practices had clear impacts on microplanning, registration, and training activities in MR campaign. For HSS, the challenges appear to be related to unclear roles and responsibilities and complicated bureaucratic process, though details remain to be clarified. Elections and political transition were also main drivers of funds going unspent and activities not being completed.

Clear contingency management for funds approval and disbursement are important steps toward avoiding future bottlenecks in NUVI and HSS. Gavi Secretariat may also explore with countries how to strengthen mechanisms around technical assistance from partners and accountability of country stakeholders regarding implementation of NVS and cash-based support.

Limited vaccine storage capacity

Limited vaccine storage capacity also raises questions about cross-cutting effects on NUVI in Bangladesh. During the MR campaign, additional public storage facilities were used to accommodate MR vaccine inventory, including space that had been allocated for PCV. Notably, utilizing PCV space was feasible because PCV introduction had been postponed. However, it raises the question about whether the system would have coped as well had PCV already been in-country. Limited vaccine storage was also a key factor in the selection of HPV vaccine for the demonstration project in 2015. Bivalent HPV vaccine, using a two-dose vial, requires much less space than the quadrivalent preparation, which uses a one-dose vial. Addressing improvements in cold-chain capacity have been flagged as a key priority of HSS support stream.

Negative effects of political unrest

Political unrest was a major challenge. During MR campaign *hartals* hampered transportation and delivery of vaccines and logistics to sites, limited health worker mobility, cut training activities short, and stalled registration. Elections and government transition, another form of political unrest, led to a long delay in mobilizing the first tranche of HSS funds to key MOHFW departments. Examples described earlier from MR campaign demonstrate the ability of stakeholders and partners from central level down to manage the various obstacles. Given the nature of political unrest in country, it will be important for GOB to use lessons learned from MR campaign and HSS to develop clear contingency management plans for EPI to ensure that implementation activities do not suffer from turbulent political climates. At the same time, considering that the ability to adapt to challenges often stems from experience, investment in retaining human resources from the central level down will also enable flexible response to critical challenges that may arise in upcoming NUVI (e.g., PCV, IPV) and demonstration (HPV).

Human resource capacity and partnership

Strong human resource (HR) capacity and partner engagement was evident during MR campaign and draws on a depth of experience of EPI from past programs. The measles catch-up campaign in 2006 demonstrated for the first time the capacity of health workers to administer vaccine by injection on a large scale. Previous campaigns (e.g., polio, vitamin A, deworming) involved only oral administration. This capacity was also evident in the MR campaign, which required an exceptionally large number of skilled vaccinators from multiple sectors (e.g., NGOs, hospitals, medical colleges, nursing institute, and volunteer organizations).

EPI also drew on prior experience with school-based campaigns (e.g., during measles follow-up in 2010) to design an appropriate school-based component for MR campaign. Survey results showed that more children received MR vaccine through school-based delivery than EPI based delivery. Lessons on the successful design for MR campaign should be carried forward to inform the design and implementation of school-based vaccine delivery for the upcoming HPV vaccine demonstration in 2015.

Strong HR capacity for managing challenges is also evident in various example from MR campaign. At a high-level, the Minister of Health devised a strategy to ensure that funds could be mobilized. At the subnational level, health workers took initiative to keep registration activities on track by improvising registration forms until the prescribed forms arrived. With respect to insufficient ice packaging for vaccine storage during the MR campaign, stakeholders collaborated with ice-cream factories to ensure that cold-chain could be maintained.

Effective partnership was also noted. One example was the assistance provided by WHO to hire extra vehicles to navigate transportation challenges during MR campaign during a period of strikes. Social mobilization activities for MR campaign also benefitted from strong local partnerships, for example with non-governmental and volunteer organizations. Additionally, as indicated above, strong intersectoral engagement enabled the availability of large numbers of skilled vaccinators during the MR campaign.

Conclusion

Conclusions from the Gavi FCE in Bangladesh can be drawn based on the two main focus areas for this evaluation period: MR campaign evaluation and HSS.

The MR campaign conducted by MOHFW was the largest campaign conducted globally to date; it was successful in terms of coverage, antibody status, quality of services, providers' perspectives, quality of implementation, and recipients' perspectives. These successes relate to a number of factors that should be considered in the context of upcoming Gavi-supported NUVI and in routine EPI as well as for other countries implementing similar campaigns.

First, GOB showed strong political commitment to the introduction of MR campaign. On the one hand, this was evident in the government's recognition of the rubella disease burden and the prioritization of MR campaign, to complement routine MR activities. On the other hand, faced with a budgetary delay, the Minister of Health and Family Welfare took initiative to adjust the MR campaign budget in order to release funds for disbursement. This resulted in only a minor delay to the launch of the Campaign.

Second, despite some challenges, the successful implementation of MR campaign was supported by a dedicated workforce. For example, to mitigate delays in the arrival of registrations forms, health workers improvised forms, which enabled the mobilization of registration activities. In addition, EPI service providers expressed widespread satisfaction about participation in the campaign.

Third, adaptive management strategies at different levels of EPI were notable factors that contributed to a successful launch. The ability to manage the vicissitudes of political unrest, challenges with cold-chain space and logistics, and intermittent stock-outs indicate strong capacity of EPI. The government should aim to maintain and build on existing workforce at different levels for ensuring successful NUVI in the future.

Fourth, EPI program capacity was also bolstered by strong partnership at different levels and, by extension, the pro-activity of partners around preparation for the Campaign. Examples of this include

WHO helping to mobilize vehicles to deal with transportation challenges due to political unrest, the strong presence of CSOs like the Lion's Club in social mobilization activities, involvement of health workers from multiple sectors in vaccination activities, and strong relations with the media that encouraged responsible public messaging around suspected AEFIs.

Despite the success, there were some limitations of the Campaign, with around 10% of children not vaccinated reflecting inequalities in coverage and suboptimal levels of registration.

Regarding HSS, the proposal designated HSS funds for addressing critical constraints on Health, Nutrition, and Population Sector Program (HNPS 1996-2011) targets. The overarching aim was to ensure that community clinics, the back-bone of the new operational strategy for PHC, had the minimum functional capacities and infrastructure to deliver safe and effective maternal and child health and immunization services.

In 2009 Gavi disbursed funds for the first tranche of HSS funds to the Planning Department of the MOHFW. The funds remained unspent for almost two years due to a number of factors at the central and global levels. Changing financial management policies and processes at Gavi resulted in delays in HSS implementation across multiple countries. At the country level, a combination of limited awareness of the FMR guidelines, challenges related to staff turnover, and concerns about the changing national health strategy as a result of a newly elected national government may have contributed to the delayed disbursement of HSS funds.

As result, implementation activities around recruitment, health worker training, and infrastructure development for community clinics were not carried out. It is important to note that for HSS, we are midway through the evaluation and further results will be presented in future Gavi FCE reports. For details of the upcoming planned evaluation activities, refer to the Gavi FCE 2014 annual progress report.

Positive and negative unintended consequences of Gavi support

At this stage in the Gavi FCE, we have evaluated the MR campaign in detail but have yet to employ more in-depth evaluation methods surrounding the other streams of funding, as they are largely in a preliminary stage. Consequently, we have yet to identify broader positive or negative unintended consequences of other streams.

However, from the MR campaign, as in other settings,²² we note some positive impacts on routine EPI: improved communication; procurement of additional supplies; improved healthcare worker confidence and motivation; and reduced fear of vaccination in the community. Other negative impacts of MR campaign on EPI were monitoring activities of routine EPI (i.e., greater demands on health workers' time), and in some cases failure to fulfill routine vaccination programs. The FCE team will continue to evaluate the positive and negative unintended consequences of Gavi support moving forward.

Chapter 3: Mozambique

Mozambique

Gavi support for Mozambique

The Mozambique Expanded Program on Immunization (EPI) was launched in 1979 under the Primary Health Care Program. Gavi support in Mozambique began in 2001 with Immunization Support Services (ISS) and New Vaccine Support (NVS) disbursements preceding the introduction of tetra DPT-hep B. Over the past 14 years, Gavi has disbursed a total of US\$99.6 million to Mozambique. This funding supported vaccination efforts and has been available as cash support in the form of the ISS grant, which ended in 2012.

Most recently, Gavi supported the introduction of pneumococcal conjugate vaccine (PCV) in 2013 and is currently supporting the human papillomavirus (HPV) vaccine demonstration project in Manhica, which began in 2014. Cash support for Health system strengthening (HSS) has been approved and implementation was scheduled to begin in 2014, but has not yet commenced. Rotavirus and measles second dose (MSD) vaccines are scheduled for introduction in 2015 and are also supported by Gavi. An inactivated polio vaccine (IPV) application was submitted in 2014 and its introduction is expected to take place in 2015.

Table 14: Streams of Gavi support

Gavi funding stream	Period of funding	Total amount of funding (US\$)
Pneumococcal conjugate vaccine (PCV)	2013-2016	60,763,092
Pentavalent vaccine	2001-2007*; 2009-2015	58,369,882
Human papillomavirus (HPV) vaccine (demonstration or national)	Demo 2014-2015	98,503
HPV vaccine cash support	2014-2015	195,000
Health system strengthening (HSS)	2014-2018	25,041,767
Immunization services support (ISS)	2001-2003, 2011	1,665,500
Injection safety support (INS)	2003-2005	835,881
Rotavirus vaccine	2015-2018	19,678,000
Inactivated polio vaccine (IPV)	2015-2018	5,007,500
Measles second dose (MSD)	2015-2018	2,388,000
Vaccine Introduction Grant (VIG)	2002, 2007, 2012, 2015	3,799,500

Source: <http://www.gavi.org/country/all-countries-commitments-and-disbursements>, accessed last April 21, 2015*Earlier phase of support was for tetra DPT-hep B

Values shown represent Gavi commitments, those which Gavi intends to fund over the life span of the program, subject to performance and availability of funds.

Methods overview

Consistent with the prospective nature of the FCE, the evaluation has reflected Gavi-supported activities, assessing implementation and related milestones by support stream. Table 15 provides an overview of the methods used, the sources of data, and the topics assessed by these methods.

Table 15: Evaluation methods

Methods	Source Consulted	Topics Investigated
Process Tracking	<ul style="list-style-type: none"> - Collected and reviewed documents including Gavi applications, Gavi decision letters, operational plans and budgets, meeting minutes, Gavi communication letters, vaccine implementation guidelines, data sets from the Ministry of Health (MOH), and other literature. - Conducted brief interviews to confirm factual information with stakeholders at the National Immunization Programme (NIP), WHO, and UNICEF. - Observed NIP meetings, a NIP teleconference with the Gavi Secretariat, and HSS planning meetings, and retreats. 	<ul style="list-style-type: none"> - Information was collected based on relevant Theory of Change (TOC) milestones for PCV, HSS, HPV, and IPV, including: <ul style="list-style-type: none"> o Planning and budgeting for national HPV vaccine demonstration o Establishment of denominator o HSS operational planning development o Routinization of PCV o Planned allocation and expenditures of HSS monies
Key informant interviews (KII)	<ul style="list-style-type: none"> - Conducted 23 country-level KIIs at the national level and in Manhiça district, with government (fifteen, of which eight were from Manhiça district), Gavi partners (4), NGOs (3) and health research center (1). - Conducted 10 KIIs with global-level staff from the Gavi Secretariat and Alliance partners. 	<ul style="list-style-type: none"> - Information was collected based on relevant TOC milestones for PCV, HSS, HPV, and IPV.
Analysis of administrative data on vaccine coverage	<ul style="list-style-type: none"> - Used Módulo Básico and NIP vaccine coverage data. 	<ul style="list-style-type: none"> - Scale-up and routinization of PCV
Small area analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey and census data sources. 	<ul style="list-style-type: none"> - Estimation of district and province level vaccine coverage and child mortality
Inequality analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey data sources of household wealth and vaccination coverage. 	<ul style="list-style-type: none"> - Estimation of vaccine coverage differences by wealth quintile and gender

Findings

The FCE compiled and systematically analyzed relevant data to estimate country performance along key indicators at the national and, when possible, the subnational level (Table 16, Table 17, Table 18).

Table 16: Country characteristics of Mozambique

Characteristic	
Demographic and economic indicators	
Total population (2013)	25,947,050
Birth cohort (2013)	1,005,489
GDP per capita (2014)*	US\$893
Health spending and Development Assistance for Health**	
Government Health Expenditure as source	US\$213M
Development Assistance for Health, channeled through government	US\$138M
Development Assistance for Health, channeled through non-government entities	US\$296M
Total Development Assistance for Health	US\$434M

*GDP per capita source: IHME covariates database, reported in 2005 international dollars

** Health expenditure is explained in terms of government health expenditure as source (GHE-S), Development Assistance for Health (DAH) channeled through government (DAH-G), and DAH channeled through non-government entities (DAH-NG). GHE-S + DAH-G gives the total government health expenditure, GHE-S + Total DAH gives total spending on health in the country. Health expenditure estimates 2011; Gavi disbursements 2001–2012.

Table 17: Vaccine coverage estimates in Mozambique

Vaccine coverage	Most recent survey estimate*	WUENIC 2013 revision**	Self-Reported Coverage (WHO)***
DPT/Penta3 coverage	76.2%	78%	78%
DPT1-DPT3 dropout rate	15.1%	15%	15%
BCG coverage	91.1%	93%	93%
Polio3 coverage	73.2 %	78%	78%
Measles coverage	81.5 %	85%	85%
Percent fully vaccinated****	64.1 %	N/A	N/A

* Most recent survey coverage estimates from 2011 DHS

** WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) 2013¹³

*** WHO vaccine-preventable diseases monitoring system, 2014 global summary¹⁴

**** BCG, measles and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth).

Table 18: Child, adult, and vaccine-preventable disease mortality in Mozambique

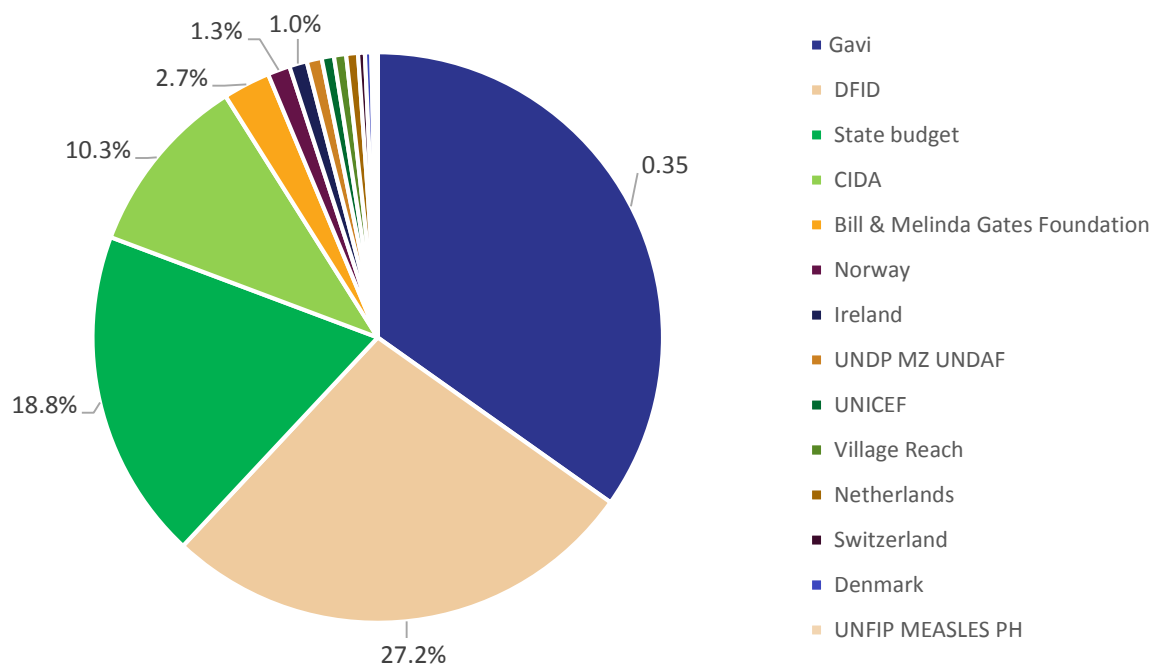
Child, adult, and vaccine-preventable disease mortality	GBD2013*
All-cause mortality (risk per 1,000)	
Infant mortality (_{1q0})	60.1 (50.2, 70.2)
Under-5 mortality (_{5q0})	88.4 (76.9, 101.5)
Female adult mortality (_{45q15})	367.2 (344.8, 390.9)
Male adult mortality (_{45q15})	278.6 (215.5, 361.8)
Cause-specific mortality: children under 5 (rate per 100,000)	
Measles	18.2 (4.4, 53.5)
Diphtheria	0.13 (0.00-0.68)
Tetanus	6.1 (3.4-10.8)
Pertussis	11.4 (0.0-60.0)
Meningococcal infection	5.0 (2.8-8.1)
Diarrheal disease	107.5 (60.9-175.0)
Lower respiratory infections	198.9 (134.3-273.7)
Cause-specific mortality: all ages (rate per 100,000)	
Cervix uteri cancer	3.3 (2.5, 4.5)
Acute hepatitis B	0.6 (0.8-1.6)
Cirrhosis of the liver secondary to hepatitis B	2.5 (1.6-3.6)
Liver cancer secondary to hepatitis B	0.8 (0.5-1.1)

* Mortality based on GBD2013 estimates

Resources used for immunization

The FCE conducted a detailed resource tracking study in Mozambique. The 2014 resource tracking study was an EPI expenditure accounts exercise, which adapted the 2011 System of Health Accounts (SHA) methodology and estimation techniques to estimate the total envelope of resources for immunization activities in 2013. For detailed methods and results, see Annex 8.

The primary funding sources for immunization in Mozambique are Gavi, United Kingdom Department of International Development (DFID), and the state budget (government of Mozambique), as shown in Figure 21. Financing sources are defined as institutions or entities that contribute funds to finance health care. Financing for immunization activities in Mozambique includes the government and donors, as there is no private spending on immunization services due to free provision of services. These results are restricted to a single time point; follow-up studies will be conducted to look at financial flows in later years. At this point, the FCE cannot comment on whether spending by the government of Mozambique has increased or decreased relative to external donors. It is notable, however, that external donors contribute two-thirds of the overall resource envelope for immunization.

Figure 21: Immunization funding sources for fiscal year 2013 in Mozambique

Using funds for immunization, ambulatory health care centers were the providers spending the majority of immunization funds in Mozambique (US\$17,849,234), followed by providers of public health programs through districts mainly (US\$3,588,006), and providers of public health programs at the central level (US\$2,161,204). Further studies analyzing expenditure to the level of the health facility are planned for 2015 onward and will be included in Mozambique's Gavi FCE health facility survey, set to take place in 2015.

The majority of funds were allocated towards special and routine immunization activities (US\$17.5 million and US\$4.9 million respectively) as illustrated in Figure 22 and Figure 23. Furthermore, our findings reveal that external assistance tends to provide support for special immunization campaigns² while the government prioritizes support to routine immunization activities. In line with this finding, more than 95% of Gavi funding supports special immunization campaigns.³

² "Special immunization campaigns" refer to expenditures related to new vaccine introductions and campaigns, which include vaccines, materials, training, supervision, special radio spots, and all activities undertaken during national campaigns.

Figure 22: Funding sources by services in Mozambique, 2013

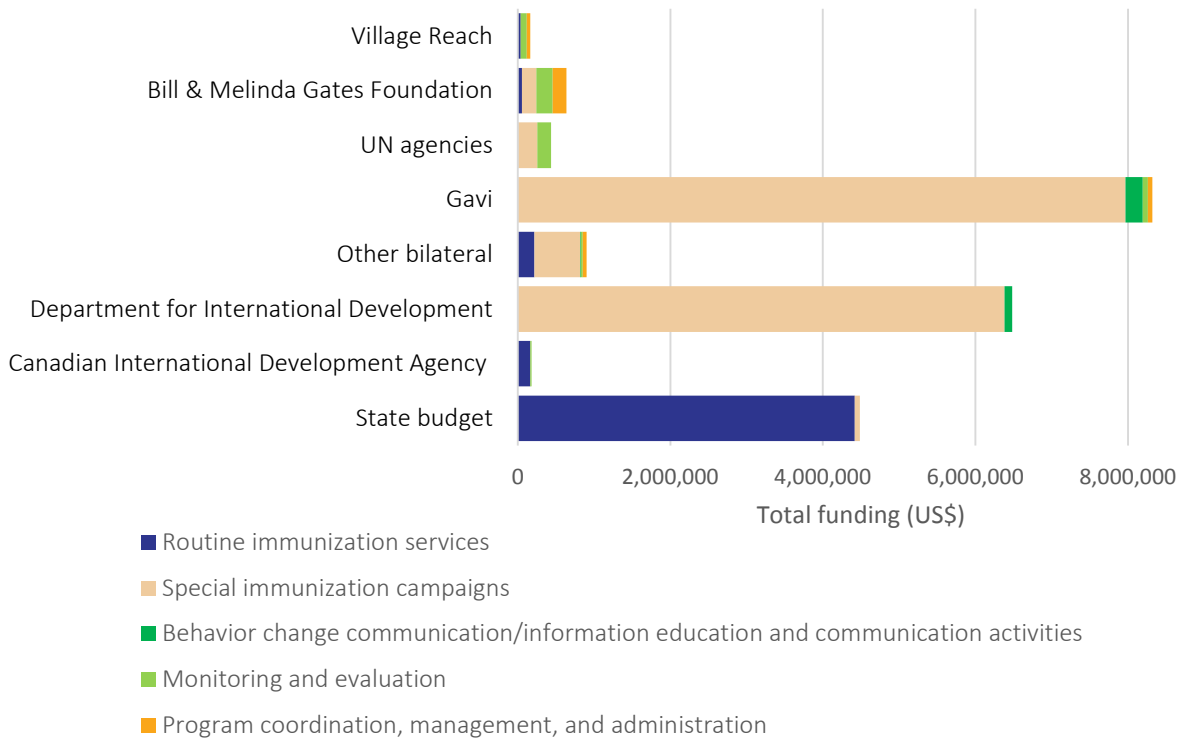
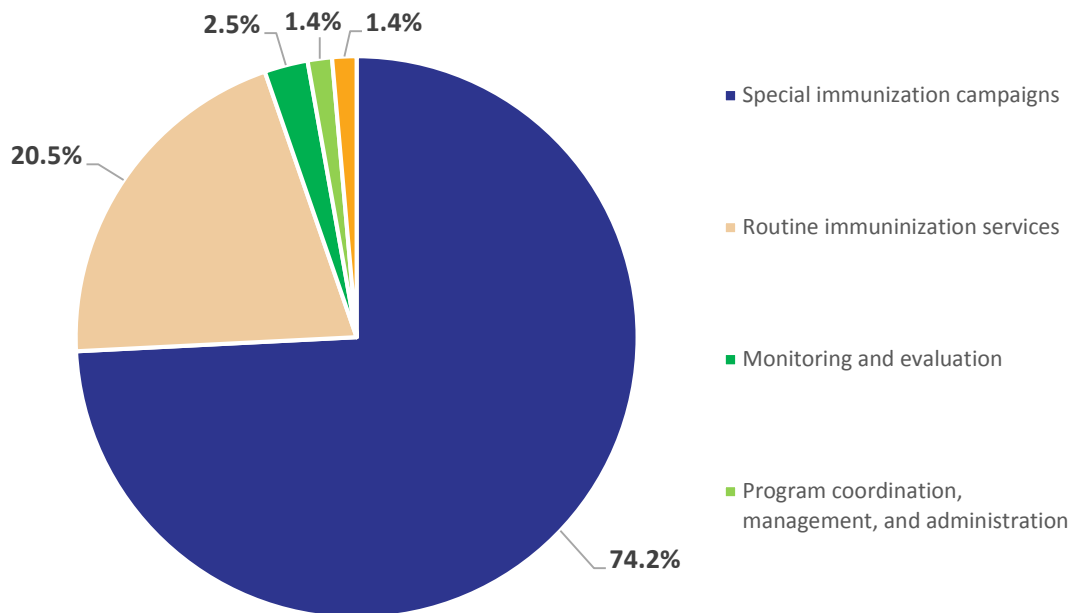


Figure 23: Total direct immunization by services (functions) in Mozambique, 2013



Analysis of immunization coverage, child mortality, and inequality

The FCE systematically compiled and analyzed available data sources to estimate immunization coverage and child mortality by geography, household wealth, and gender. These estimates should be interpreted with caution. In some cases different surveys give disparate results, suggesting data quality issues. Additionally, not all data are identified at the lowest geographic level.

In Mozambique, the national-level estimates of vaccine coverage (Table 17) mask highly variable coverage rates across the country (Figure 24 and Figure 25). Provincial-level estimates also highlight differential trends over time by province between 2000 and 2013. DPT3 coverage in 2013 was above 70% for all provinces, with highest levels of coverage in Maputo province in the south and Niassa in the north. For the fully vaccinated child (received Bacillus Calmette–Guérin [BCG] vaccine, three doses of oral polio vaccine, three doses of DPT, and measles vaccine), coverage was notably lower in the Zambézia and Inhambane provinces and Maputo city, with the latter driven by low polio coverage rates. Annex 3 provides provincial level maps for 2000 and 2013 for all antigens.

Figure 24: Province-level DPT3 coverage in Mozambique, 2000 and 2013

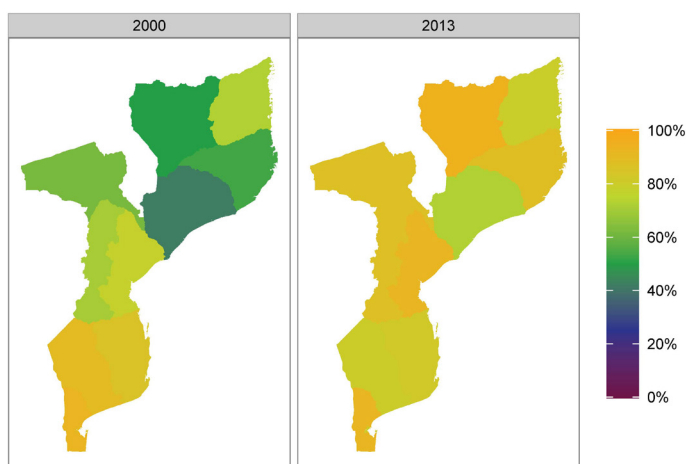


Figure 25: Province-level fully vaccinated child coverage in Mozambique, 2000 and 2013

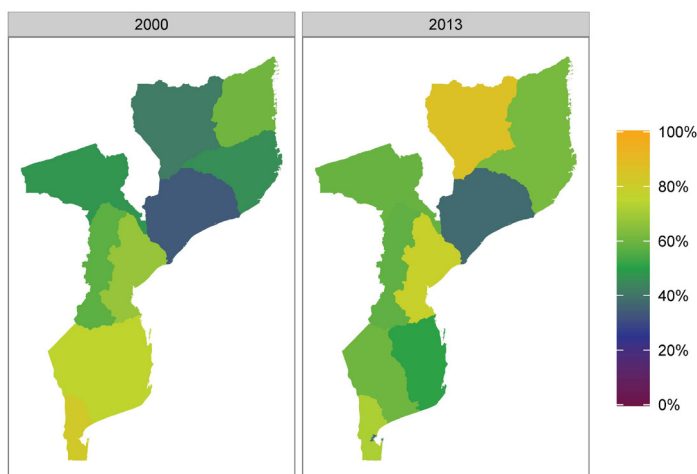
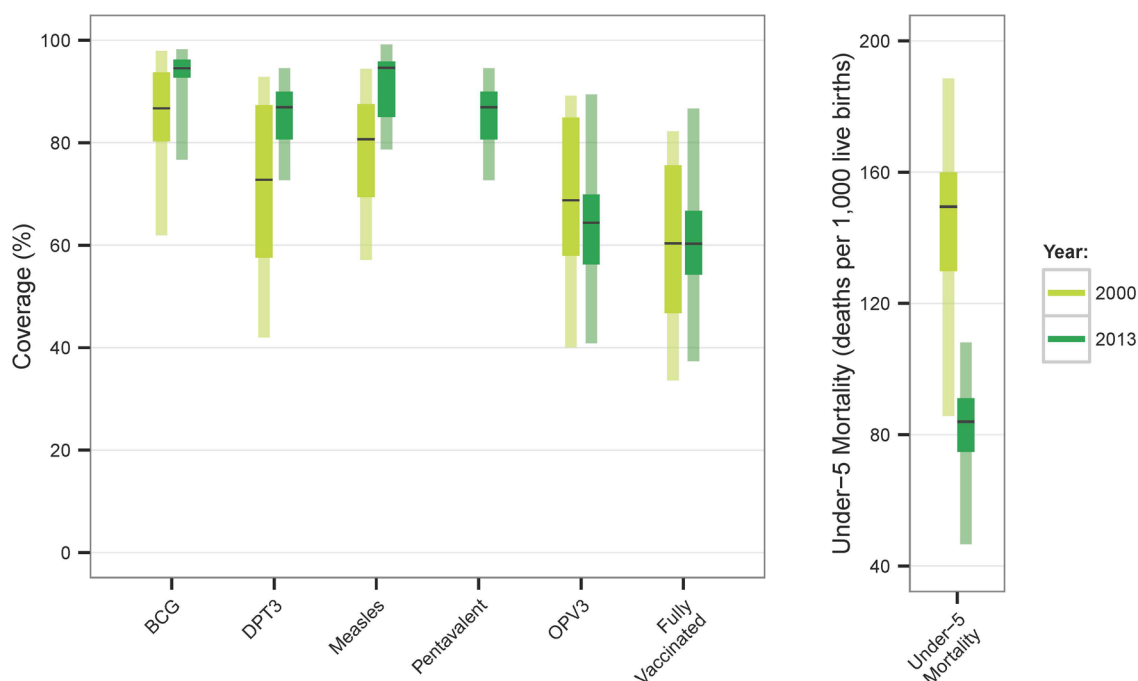


Figure 26 summarizes the distribution of the province-level estimates of vaccine coverage for 2000 and 2013 across the vaccine antigens. These results show that the median level of coverage at the province level has remained more or less the same over time for full vaccination. Results also show that there have been some declines in the median coverage for polio vaccinations. Geographical inequality, as denoted by the interquartile range, is generally decreasing over time.

Figure 26: Distribution of the province-level vaccine coverage and under-5 mortality in Mozambique, 2000 and 2013

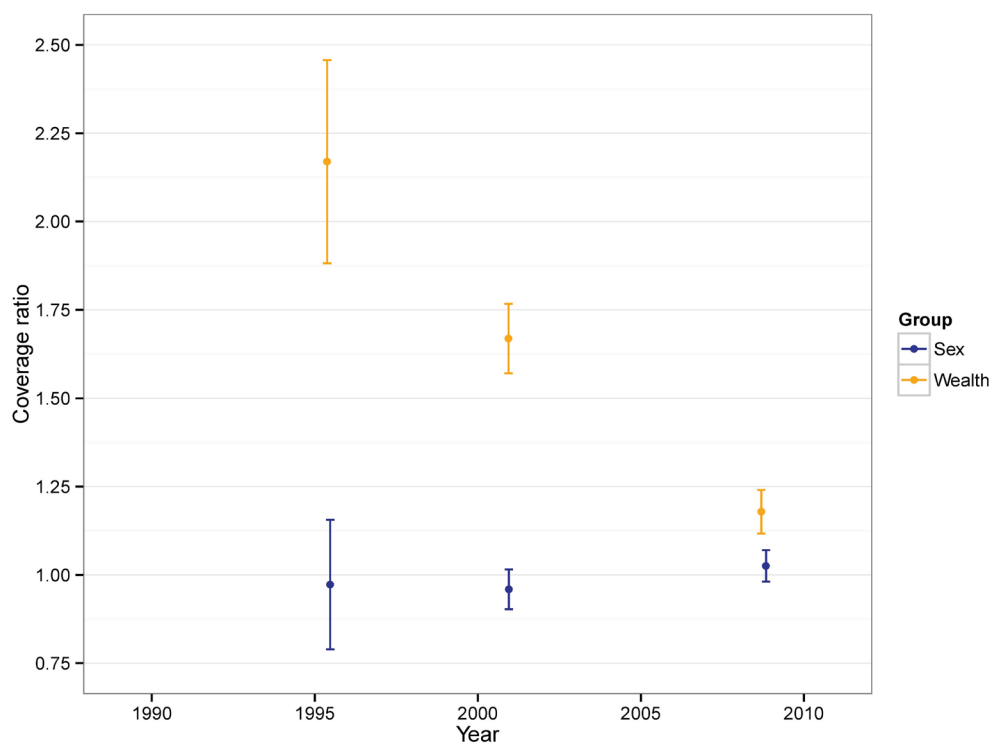
The horizontal line represents the median across provinces. The thick vertical bar represents the interquartile range, while the thin vertical bar represents the range across provinces.



In addition to geographical inequality, we observed inequality by household wealth (Figure 27). While the ratio of DPT3 coverage in the richest quintile compared to the poorest quintile has declined over time, this ratio remains significantly above one based on the latest survey (2011 DHS). Figure 27 shows, however, that DPT3 coverage is equal between males and females.

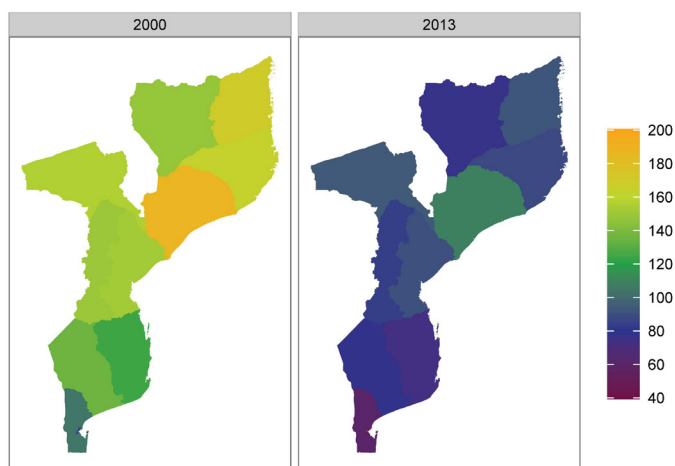
Figure 27: DPT3 coverage by wealth quintile and sex in Mozambique

Wealth ratio is the ratio of DPT3 coverage in the richest quintile to coverage in the poorest quintile. Sex is the ratio of DPT3 coverage in males versus females.



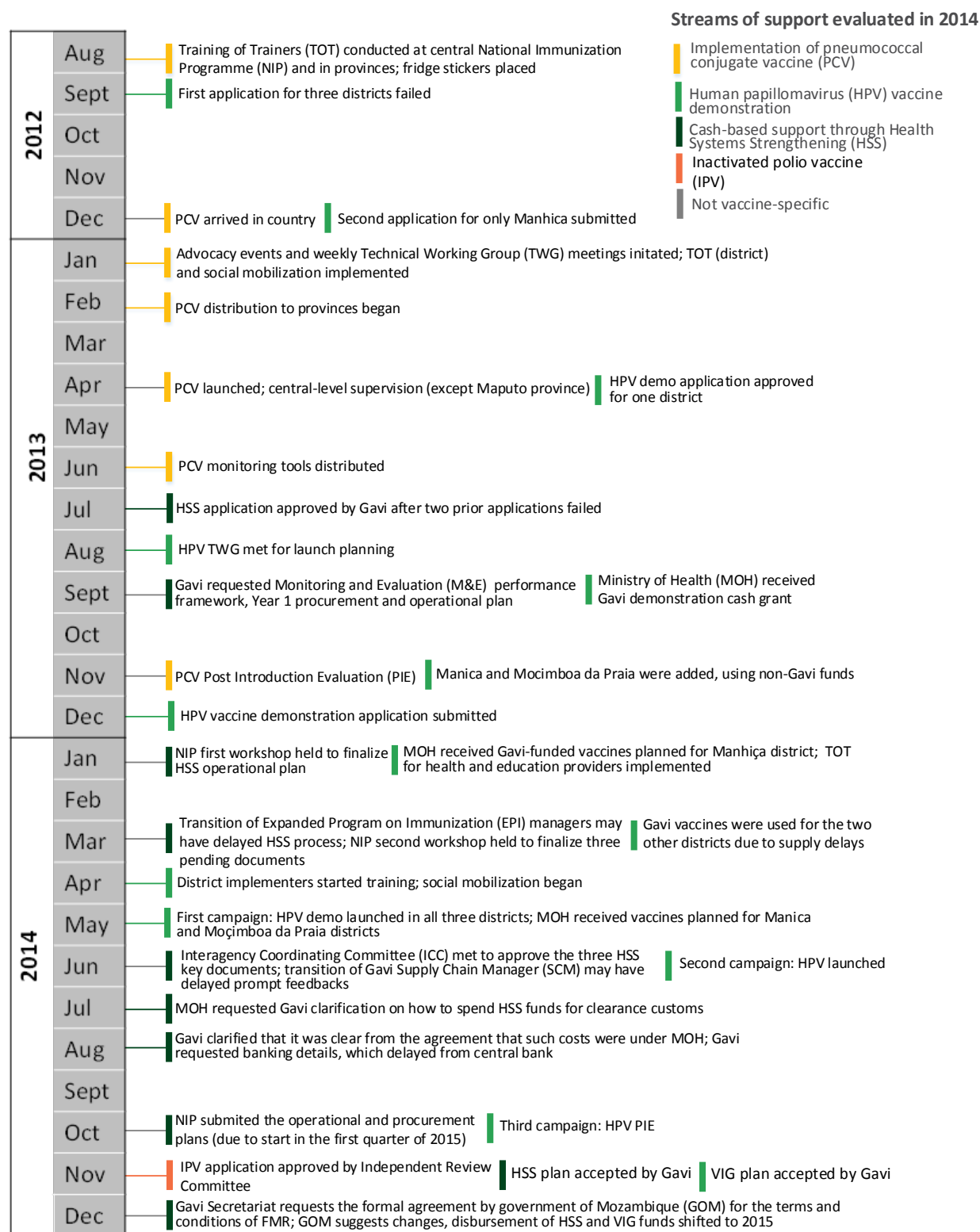
National-level estimates of under-5 mortality (Table 18) also mask considerable variation in province-level under-5 mortality in Mozambique (Figure 26 and Figure 28). We observe consistent and large declines in child mortality across all provinces. Notably, child mortality is highest in Zambézia province, which was also identified as having especially low coverage of full vaccination.

Figure 28: Province-level under-5 mortality in Mozambique, 2000 and 2013 (deaths per 1,000 live births)



Overview of major immunization events

Figure 29: Timeline of major immunization events in Mozambique



* EVMA occurred in May 2012

Human papillomavirus vaccine (HPV) demonstration project

Summary of progress

Mozambique first applied for Gavi support to conduct a HPV vaccine demonstration project in October, 2012. After a second round of application and approval in May 2013, the country finally launched the project in May 2014.

It appears that the decision to conduct a HPV vaccine demonstration project was not part of Mozambique's immunization planning until just prior to the first application, as the activity was not included in the country's comprehensive Multi-Year Plan (cMYP) 2012-2016. Despite this, with one of the highest burdens of cervical cancer in the world, there was strong motivation in Mozambique to leverage Gavi support to conduct a HPV vaccine demonstration project. In its first application, the country proposed to include three geographically distinct districts in the demonstration project: Manhiça in the south, Manica in the central region, and Mocímboa da Praia in the north. Gavi did not approve this application, citing concerns about the country's capacity to carry out such an ambitious demonstration project in light of other key priorities in the country.

In January 2013, Mozambique resubmitted their application for the HPV vaccine demonstration project. This application was in line with recommendations from Gavi, targeting only Manhiça district and including the Manhiça Health Research Centre (CISM) in the role of project manager. This application was approved in May 2013 with a corresponding plan to launch the demonstration project in April 2014.

Late in 2013 and in light of the decision by Gavi to only support the Manhiça district for the HPV vaccine demonstration project, the government made the decision to use its own funding to include Manica and Mocímboa da Praia in the demonstration project as was originally planned. The HPV vaccine demonstration project was officially launched on May 14, 2014 in the three districts. Three doses were administered in one-week school campaigns as follows:

- First dose: May 14 to 22, 2014
- Second dose: June 23 to 27, 2014
- Third dose: October 27 to 31, 2014

Given that the main HPV administration was conducted in schools, the Ministry of Education played a crucial role as a member of the NIP Technical Working Group (TWG) at the national level, as well as through its provincial- and district-level school health representatives and its school teachers.

The HPV administration strategy included active search in the week following the school campaign to locate and vaccinate children who did not attend the school-based HPV vaccination campaign. Additionally, during the second and the third dose campaigns, children who were not identified in the previous campaigns were also included. The Post Immunization Evaluation (PIE) for the demonstration project was recently implemented, concurrent with the third dose administration. Findings from the PIE will be reviewed as part of the 2015 evaluation period. Table 19 summarizes the progress, successes, challenges, and responses associated with the preparation and implementation of the HPV vaccine demonstration project.

Table 19: Summary of country progress

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Appropriate program design for delivery of HPV vaccine established	
<ul style="list-style-type: none"> - Second HPV proposal was approved in 2013 for a 2014 implementation. - NIP planning for HPV launch was initiated in September 2013. - Mozambique's second application for HPV vaccine was approved by Gavi. - The NIP decided to target girls born in 2004 (to complete or with 10 years of age), rather than on school grade, given that school grades can include a wide range of age cohorts. 	<ul style="list-style-type: none"> - Mozambique originally applied to conduct the demonstration project in three districts: Manhiça, Manica, and Mocímboa da Praia. However, citing many competing priorities and limited capacity within the NIP, Gavi encouraged Mozambique to implement in fewer districts. - Approval was received from Gavi to conduct the demonstration project in Manhiça site. - Manhiça is a unique site, therefore, demonstration activities are less likely to provide representative learning for national introduction.
Timely and adequate plan and budget for HPV vaccine demonstration developed	
<ul style="list-style-type: none"> - TWG convened for HPV vaccine demonstration launch in fourth quarter of 2013, and continued with weekly meetings to budget and plan. - Weekly TWG meetings for HPV vaccine demonstration were convened, beginning in late 2013. - A work plan and detailed budget were developed after the application was approved. - Despite having Gavi funding for only one demonstration district, the government decided to move forward with the original plan and implement HPV vaccine demonstration in Manica and Mocímboa da Praia, in addition to Manhiça. - Additional funding for Manica and Mocímboa da Praia was leveraged by the government from PROSAUDE.* - A survey targeted to girls and adolescents was conducted to assess willingness to participate in a HPV vaccination program and assess actual knowledge and sexual behaviors about sexually-transmitted infections and HPV. 	<ul style="list-style-type: none"> - The decision by government to include Manica and Mocímboa da Praia came late in the planning process (in November 2013). - Because of the late decision, the 2014 MOH-approved budget did not include HPV activities for Manica and Mocímboa da Praia. - Centralized planning for Manica and Mocímboa were initially based on plans and experience from Manhiça. - Much planning time was spent during the weeks leading up to the launch to plan and conduct an improvised census of the target cohorts in each district. This was not a planned or budgeted activity. Results from this activity were not used.
Appropriate technical assistance provided	

<ul style="list-style-type: none"> - HPV Technical Working Group (TWG) convened regularly. - Technical assistance from HPV TWG members and other stakeholders was provided once requested by NIP, specifically to organize financial distributions to specific stakeholders. - National Institute of Health (INS) quickly integrated into the HPV vaccine technical team. - INS assigned as technical leadership for census of 10-year-old girls and immediately began to plan for this activity in the three districts. 	<ul style="list-style-type: none"> - Limited and underutilized preliminary technical guidance from Gavi Secretariat and Alliance partners contributed to a slow-down of the implementation process (e.g., no guidelines, tools, or hands-on technical assistance/advisors detailing vaccine implementation recommendations, such whether to conduct a census for target population). Evidence from KIIs indicates that technical assistance was offered, but not accepted by the country until well into the implementation process. - INS joined the HPV TWG after government decision to include Manica and Mocímboa da Praia. - Lack of technical guidance on the appropriateness of conducting a census in demonstration districts prior to the launch.
Sufficient funding available in time	
<ul style="list-style-type: none"> - Funds to support demonstration activities in Manhiça (US\$170,000) were disbursed to Mozambique in October, 2013. In contrast to the country's experience with PCV introduction and the timing of the vaccine introduction grant (VIG), the cash grant from Gavi arrived in the country well in time for preparation activities for HPV. - Government funds for Manica and Mocímboa da Praia (US\$217,509 as of November 2014) were made available. Government spent additional US\$46,881 for Manhiça district as of November 2014. - Village Reach allocated additional funds for Mocímboa da Praia (US\$5000) of which US\$600 were allocated to Manhiça district. - Gavi funds for the HPV vaccine demonstration project arrived at MOH early in the planning process. - Village Reach responded to gap in financing for Mocímboa da Praia when it was observed during implementation of the first dose. 	<ul style="list-style-type: none"> - At the request of the MOH, Gavi disbursed funds for Manhiça district to the MOH instead of WHO, as had been planned in the application. While this resulted in better alignment with the principles of Gavi support, this led to delays in funds reaching the implementers on time because of confusion surrounding roles and transfer procedures. - Government delayed in transferring funds for Manica and Mocímboa da Praia districts to the subnational levels.
Successfully preparation and implementation of demonstration project	
<i>Actions establish cold-chain and logistic system to store, distribute and deliver vaccines in target sites</i>	

<ul style="list-style-type: none"> - Prior assessment of cold-chain and logistics system in all three districts was done by the MOH/stakeholders as part of the grant proposal submitted by NIP. - Gavi-procured vaccines for Manhiça district arrived in country on January 22, 2014. - Amount of the Gavi HPV vaccine was sufficient to cover all three districts for the first dose. - Government vaccines were used to “pay back” the doses used in Manica and Mocímboa da Praia. - Refrigerator stickers were distributed early (March to April 2014) across the three districts. - The temperature of the fridges across the three districts is checked and recorded daily, including holidays and weekends, according to key informants. 	<ul style="list-style-type: none"> - Complex importation bureaucracies stalled the arrival of MOH-procured vaccines for Manica and Mocímboa da Praia (arrived in country on May 29, 2014). In response, the government made the decision to use vaccines procured by Gavi for the first dose in Manica and Mocímboa da Praia districts
<i>Actions to set appropriate targets</i>	
<ul style="list-style-type: none"> - Estimate of target cohort sizes that were included in the application were used as targets for vaccine procurement. These estimates proved to be adequate targets. 	<ul style="list-style-type: none"> - There was confusion about whether a census was necessary or required to set targets. - Last minute planning for the improvised census led to late commencement (two weeks before the launch), unclear roles, and delayed payment of per diems for teachers and community leaders to conduct the census. - Results from the improvised census ending up not being used to compute targets and coverage but were used for microplanning. - The delay in disbursement of funds from MOH central to subnational levels seems to have been one of the reasons that aggravated the realization of the "improvised census."
<i>Activities to create demand</i>	

<ul style="list-style-type: none"> - Formative assessment for social mobilization and definition of information, education, and communication (IEC) message was successfully done in January 2014. Pretesting of messages was conducted following learning from the consequences of not pretesting social mobilization messages during the PCV introduction in 2013. - In Manhiça and Manica districts the mobilization interventions were better structured and involved both local radios and community leaders without significant problems. 	<ul style="list-style-type: none"> - Activities for social mobilization began late, two weeks prior to the launch of the first dose. - Mocímboa da Praia reported more negative effects from weak mobilization efforts. For example, late per diems for community leaders led to reverse social mobilization. There were reports that leaders in Moçimboa da Praia who did not receive per diems on time for their involvement in the improvised census disseminated messages discouraging girls from going for vaccination.
<i>Activities to train health workers and teachers</i>	
<ul style="list-style-type: none"> - Trainings was conducted in a cascade (in-country WHO staff trained national Training of Trainers from NIP central staff, who then trained provincial NIP managers, district NIP managers, and direct implementers) in February 2014 for all three districts. - Training of 60 health professionals was conducted with minimal problems. - Two trainings were conducted one for teachers and one for health professionals for monitoring adverse events. 	<ul style="list-style-type: none"> - Training of school teachers was faced with many constraints: <ul style="list-style-type: none"> o Not all teachers were prepared to participate o Training materials had poor translation into Portuguese; o Practical exercises were not included; o Payment of per diem for teachers and community leaders was late; and o Time to adequately train teachers was limited. - Training on AEFIs was included in the health workers' training, but a separate training on AEFIs had to be held for teachers and was conducted late in all three districts due to delayed disbursement of allocated Gavi funds from MOH.
<i>Activities to update the monitoring tools</i>	
<ul style="list-style-type: none"> - M&E tools were developed and ready by February 2014. 	<ul style="list-style-type: none"> - Despite early completion of the development of M&E tools there was a delay in printing and making them available at health facilities before the launch due to unavailability of allocated funds at the time. - Monitoring system for adverse effects may not have been effectively implemented as no reporting of adverse events has been captured.
Timely access to accurate information on implementation status; timely and appropriate adjustments according to information	
-	

<ul style="list-style-type: none"> - Information within the TWG was provided in a timely manner and adjustments were made under extenuating circumstances. - Decisions were usually delayed to ensure buy-in from key stakeholders.
<p>Knowledge gained about the acceptability, feasibility, costs and effectiveness of the delivery program and of integrated intervention</p>
<ul style="list-style-type: none"> - CISM conducted the acceptability and awareness study in two HPV vaccine demonstration sites (Manhiça and Mocimboa da Praia). - Observations of practices during vaccination campaigns were conducted. - The feasibility assessment has recently been conducted (October 2014) as part of the PIE. Technical assistance for this activity was requested very late in the process according to one key informant. - A cost-effectiveness study was being prepared. A consultant is orienting a team since the second week of November 2014. - A coverage survey was planned to start on December 14, 2014 in Manhiça district. The government is yet to decide whether it will be conducted in other districts. <ul style="list-style-type: none"> - Results from the CISM study of acceptability and awareness had not yet been formally disseminated as the team was still finalizing the reports.
<p>Thorough assessment of potential integrated adolescent health interventions</p>
<ul style="list-style-type: none"> - Other options for delivering the HPV vaccine for example, youth and adolescent services, were discussed during the application process but thoroughly formal feasibility assessment was yet to be conducted.
<p>Demonstrated ability to deliver HPV vaccine to the target cohort</p>

<ul style="list-style-type: none"> - HPV vaccine delivered to the target cohort across three district wide week campaigns: <ul style="list-style-type: none"> o First week: May 14-22, 2014 (first dose) o Second week: June 23-27, 2014 (second dose and first dose mainly in Mocímboa) o Third week: October 27-31, 2014 (third dose and second dose mainly in Mocímboa) - Each week's campaign was followed by an active search in the following week to locate and vaccinate missing children. 	<ul style="list-style-type: none"> - Launch dates changed twice. - Mocímboa da Praia was not rigorous in checking the precise ages of the children (findings from CISM acceptability/awareness study). - High dropout rate in Mocímboa da Praia between first and third doses (28%, as compared to 7% from Manica and Manhiça) due in part because girls who had received first dose during the second campaign received second dose during the third and final campaign, with no opportunity to receive the third dose. - Target population is officially informed by National Institute of Statistics (INE) population-based census (3,350 in Manhiça), but it differs with more accurate data from Demographic Surveillance Site (DSS) (2,449 in Manhiça at the 97% district wide DSS coverage). This may affect HPV vaccine coverage estimates that use this data.
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**Note: proSaude is the "common basket" funding mechanism whereby donors may contribute to a joint fund which is then administered and managed by the MOH. It is alternately known as the SWAp.*

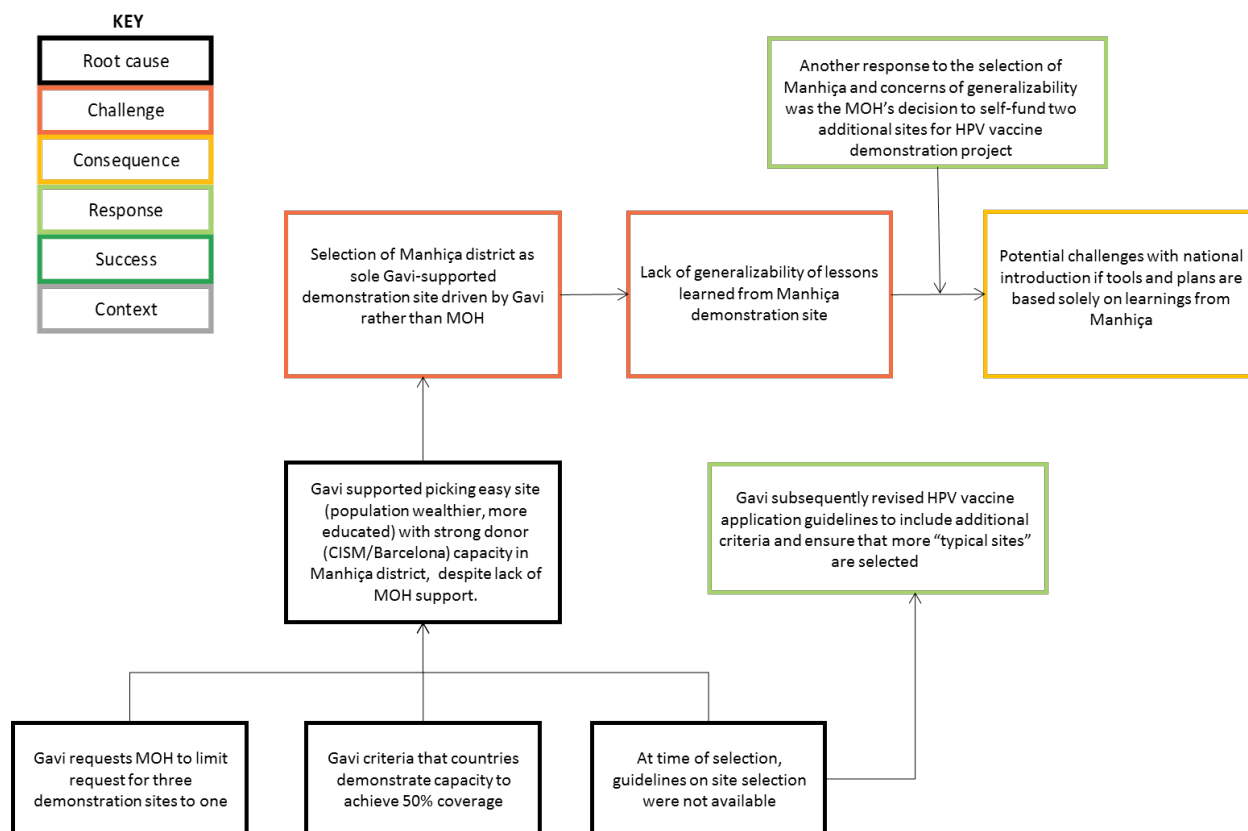
Analysis of major challenges and successes

The Gavi FCE identified three major findings from the analysis of Mozambique's application, preparation, and implementation of the HPV vaccine demonstration project which are discussed in this section.

Finding 1

The district ultimately chosen as the Gavi-supported site for the HPV vaccine demonstration in Mozambique represents a district with relatively favorable implementation conditions that include strong partner support and comparatively higher socioeconomic conditions. The government of Mozambique's later decision to include and independently fund two additional HPV vaccine demonstration districts will likely lead to lessons learned which will be more applicable and which will result in tools and plans that are better adapted for national introduction.

Despite the existence of several factors to incentivize the selection of a district in which it would be relatively "easy" to conduct the HPV vaccine demonstration project, the government and partners recognized the value of learning from experiences in delivering HPV vaccines in a diversity of settings. Figure 30 summarizes these factors, the ensuing challenges and consequences that Mozambique faced in its application and planning for the demonstration project in only one district, as well as the country's response as they recognized the importance of a demonstration project that better represents the potential challenges that may be encountered in a national introduction.

Figure 30: Root cause analysis for selection of HPV vaccine demonstration sites

In its first application for HPV vaccine demonstration support, Mozambique clearly identified a need to capture lessons learned across variety of contexts in the HPV vaccine demonstration project to “guarantee that most potential challenges in implementation can be addressed.”²⁵ Given the heterogeneity of its population, the country proposed to conduct the demonstration in three representative districts: Manhiça, Manica and Mocímbo da Praia (Figure 31). However, citing other key priorities such as the development of an HSS application, introduction of PCV, and re-application for support to introduce rotavirus vaccine and limited central level capacity, the Independent Review Committee (IRC) and Gavi Secretariat encouraged the country to pare down the scope and specifically to leverage the capacity of CISM to help manage the project.

It will be important to respond to the IRC’s concerns, for example, by establishing a program management group to take advantage of the Manhiça Health Research Centre’s project management capacity, to reduce the onus on government; and by reducing the number of districts involved in the demonstration. (Decision letter dated December 18, 2012, from Gavi CEO to Mozambique Minister of Health)

Key informants at the global level also noted that the encouragement from Gavi to simplify the project was driven by the desire for Mozambique to carry out a successful demonstration project so they would qualify for national introduction.

The government wanted to expand to various districts but Gavi was concerned that if they didn't run a good quality demo project it would affect their ability to apply for a national program.
(Global KII)

Manhiça district, in the southern region of Mozambique, represents higher levels of school enrolment and better socioeconomic conditions than the other districts initially targeted as demonstration sites (Figure 31 and Figure 32). It is also a convenient choice for conducting the HPV vaccine demonstration project, given its proximal location to Maputo city (where NIP and other key stakeholders are based), access to high quality technical assistance from CISM, and a population that is used to participating in health research. Also, prior to the HPV vaccine demonstration window of support opening through Gavi, CISM was actively pursuing funding to generate the evidence that the Mozambican government needed to conduct a national rollout of the HPV vaccine; therefore, they were well positioned for this specific learning and evaluation-driven project.

Figure 31: Comparison of various characteristics among HPV demonstration districts

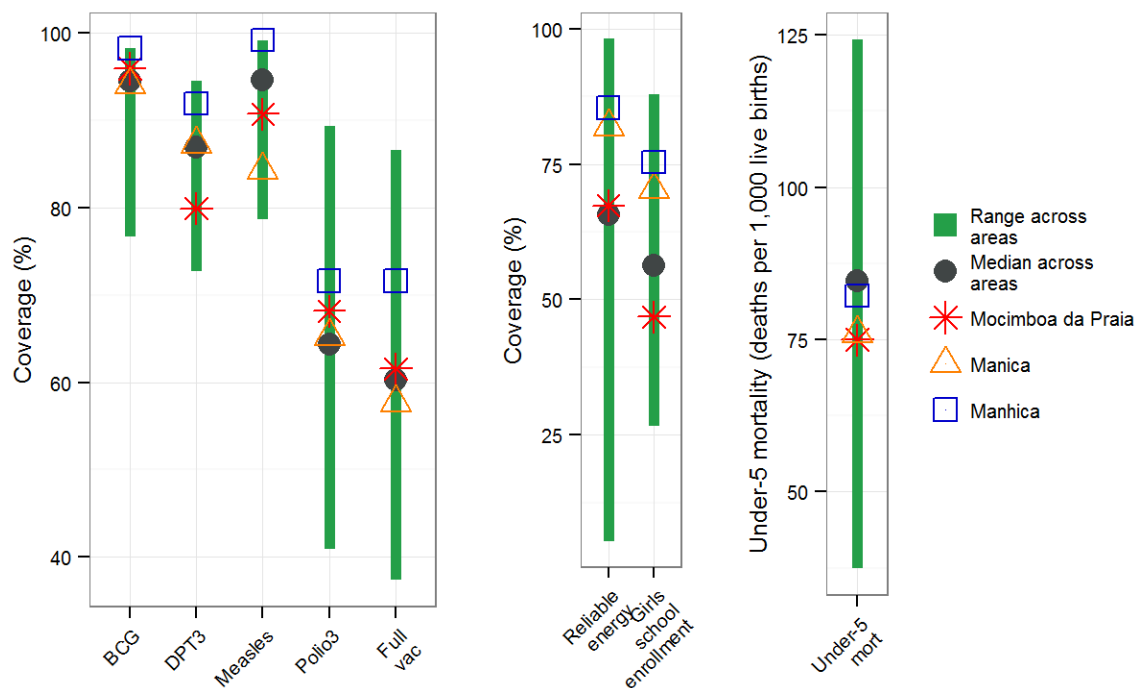


Figure 32: Health and socio-economic parameters: comparison across the three provinces containing Mozambique HPV vaccine demonstration projects implementation districts

Indicator	Maputo province (contains Manhiça)	Manica Province (contains Manica)	Cabo Delgado Province (contains Mocímboa da Praia)
Proportion of girls aged six years or more who enrolled in primary schools	64.7	63.5	46.8
Under-5 mortality (deaths per 1,000 live births)	96	114	116
Contraceptive prevalence (%) among women 15- to 49-year-old (married or in union)	32.8	12.5	2.9
Proportion of households with access to potable water	85.1	84.1	37.1
Proportion of households with access to electricity	60.3	22.2	5.0
Wealth quintile (proportion in poorest quintile)	1.2	5.5	23.8

Source: INE et al. 2013 (DHS 2011)

Convenience and all-but-explicit encouragement from Gavi to conduct the demonstration project in Manhiça likely drove the selection of Manhiça as the sole demonstration site in Mozambique's second application for HPV vaccine demonstration support. However, we note two other factors which may have contributed as well to the selection of Manhiça over Manica, Mocímboa da Praia, or another district for the demonstration. First, the technical guidance from Gavi and Vaccine Alliance partners available to the country at the time of application provided limited information or criteria for how to select districts for the demonstration project (the guidelines only stated that the district need be of "average size" and include both rural and urban areas). Specific guidance to consider criteria such as geography, socioeconomic/ethnic/cultural diversity, school enrollment and others that might facilitate identification of a district or districts that best represent the range of conditions which would be encountered in a national rollout were not present. We note that more recently published guidelines for 2014 and 2015 do include additional criteria, indicating that Gavi has recognized the need to emphasize these factors for consideration.

A second factor which could potentially have incentivized the selection of Manhiça is the requirement that countries be able to demonstrate their ability to achieve at least 50% coverage of the target cohort in the selected districts. In the case of Mozambique, this did not seem to be a factor in district selection, but we call it out as a potential factor because the incentive to achieve this coverage target is in contrast with the HPV vaccine demonstration window's objective to be a learning opportunity and may result in district selections in some countries which are not representative of the experience the country would have in introducing the vaccine nationally.

Despite the incentives to choose an "easier" district and the convenience of Manhiça as a demonstration site, Mozambique and partners repeatedly articulated the need for the demonstration

project to more broadly represent potential circumstances that would be encountered in a national introduction. Even at the time of Mozambique's second application, the Interagency Coordinating Committee (ICC) noted that "further demo projects may be needed in other geo-political sections of the country to gain needed experience prior to national application." A gradual roll out to other districts after the demonstration project was also proposed as a strategy for introducing the vaccine nationally.

Ultimately, Mozambique chose to include both Manica and Mocímboa da Praia as originally planned. However, the decision came late and was not without consequences. Challenges arose related to availability of monies to support training and development of IEC materials. Likewise, outreach efforts to effectively engage community leaders, particularly in Mocímboa da Praia, which is considerably more rural, were stymied due to late arrival of funds to support this critical outreach and education.

Recommendation

- 1. Gavi and country governments should continue to ensure that selection of demonstration sites maximizes the potential for a representative experience that may contribute to lessons learned for national introduction. This may include supporting multiple demonstration sites in a simultaneous or phased manner and/or encouraging co-financing of additional demonstration sites by country governments or other donors.**

An identified success of the HPV vaccine demonstration project in Mozambique was the decision by the government to include and fund the districts of Manica and Mocímboa da Praia in addition to Manhiça district to provide a basis for learning across a more diverse set of sites. This will likely yield lessons learned that are more applicable and result in tools and plans that are better adapted for national introduction in Mozambique. However, if that the government of Mozambique had decided not to fund the two additional sites, the potential learning for national introduction would have been substantially reduced, given the relatively favorable implementation conditions in Manhiça district.

Our recommendation is that Gavi and country governments should continue to ensure that the selection of demonstration sites maximize the potential for a representative experience. The model observed in Mozambique of co-financing a larger number of demonstration sites could be one considered for other countries. In cases where only one district is selected for a demonstration project, a phased approach to introduction may be warranted, as was recommended by the Mozambique ICC. We also noted earlier that the 2014 and 2015 guidelines on site selection have been modified to emphasize the need for a representative experience.

Robustness of finding

Finding	Ranking	Robustness Criteria
The district ultimately chosen as the Gavi-supported site for the HPV vaccine demonstration in Mozambique represents a district with relatively favorable implementation conditions that include strong partner support and comparatively higher socioeconomic conditions. The government of Mozambique's later decision to include and independently fund two additional HPV vaccine demonstration districts will likely lead to lessons learned which will be more applicable and which will result in tools and plans that are better adapted for national introduction.	B	Findings were confirmed by multiple KIs. There were, however, limited observations from the meetings where these decisions were made. Furthermore, it is an assumption that the country will garner more applicable knowledge from having three demonstration sites, but this has not yet been confirmed.

Finding 2

Insufficient technical guidance and underutilized technical assistance, coupled with the National Immunization Programme (NIP) and country-level partners' limited knowledge on implementing HPV vaccine demonstration projects led to the unsuccessful implementation of a target population census in the HPV vaccine demonstration sites, which was ultimately abandoned. The resources required to conduct the census resulted in a lack of attention being paid to other preparatory activities that affected the quality of the HPV demonstration project.

Two key challenges for Mozambique in planning and preparing for the demonstration project were insufficient technical guidance and underutilized technical assistance (Figure 33). Several key informants mentioned the lack of a specific HPV vaccine introduction manual to guide them. The FCE notes that several of the resources available on WHO's *HPV Vaccine Introduction Clearinghouse* website²⁶ are generally applicable to new vaccine introductions and not specific to HPV vaccine. There is mention of an HPV Vaccine Introduction Guide which is noted as "coming soon."²⁷ We note there are several resources that *are* specific to HPV vaccine, though given the multitude of resources available, it may be difficult for countries to identify the ones they need.

With respect to technical assistance, key informants at the global level indicated that repeated offers to provide technical assistance with implementation were extended, but were not accepted by the country until very late in the process.

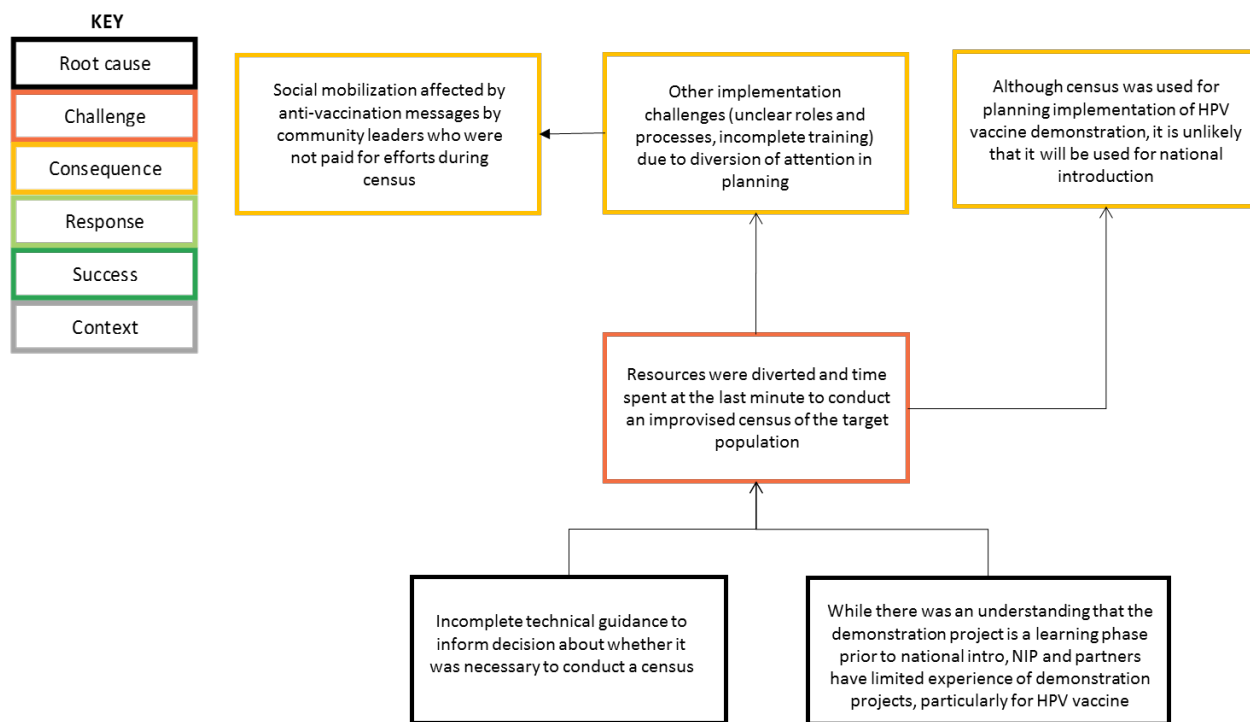
The confluence of these two factors led to a late realization that other countries had implemented a target population census as part of their demonstration projects and a subsequent decision by the TWG in Mozambique to conduct a census in the three demonstration districts.

...And then we were forced to do a census, to make sure that the number we actually had estimated corresponded to reality ... And we noted that in other countries ... they did the census exactly to determine the amount of vaccines ... so it was something that came up, it was not really planned ...because we have only received this experience too late, after doing everything... (MOH KII)

Considerable effort and time by the TWG was spent on designing and implementing a census. The National Health Institute (INS) quickly mobilized to design and develop a plan and budget for the census. The plan was subsequently rejected, however, given insufficient funds. The TWG then discussed various options and came to consensus to conduct an improvised census of the target cohort, counting eligible girls in two ways: 1) a school-based census conducted by teachers; or 2) a community-based census conducted by community leaders. The improvised census was implemented in each of the three demonstration districts.

The results of the improvised census in schools, while useful for district planning, were ultimately not useful for district coverage estimation and, due to poor data quality, the results from the census were used. More importantly, the TWG also realized that as part of any subsequent national introduction, a census of the target population would not be feasible. Clearer upfront technical guidance covering all the steps necessary to implement a HPV demonstration project and subsequent transition from the demonstration project to a nationally scaled-up program would have avoided the wasted time and resources spent on implementing the improvised census.

Figure 33: Root cause analysis for the affected quality of the HPV vaccine demonstration implementation



The effort and time spent on implementing the improvised census also had a number of important downstream consequences as summarized in Figure 33. The planning and implementation of a census

led to a diversion of resources and time which delayed other preparatory activities such as training and distribution of monitoring tools. This led to unclear roles and processes; for example, key informants noted in some schools teachers had not been trained by the time of the launch and were unsure what they should do. There were also reports of lack of clarity in how many vaccination cards to distribute to girls and where they were to be stored. Additional challenges were noted in the CISM acceptability and awareness study; for example in Mocímboa da Praia, they found that some children were vaccinated without checking their precise ages. This may have contributed to inaccurate estimates of coverage.

...in other schools there was no registration of girls who did not get the first dose, the teacher only proved orally to the vaccination brigade that the child was 10 years old. This age determination was based on estimates according to the child's physical stature, because most had no documentation, nor the proper guardians knew for sure the age of the girl, or the year in which she was born. (CISM 2014 preliminary report of HPV vaccine acceptability/awareness study)

A second consequence was that the census activity itself was rushed and not well planned or funded. The results were poor quality data that was not used and the emergence of some counter-vaccination messages by community leaders who had not been remunerated for their participation in the census. This contributed to low first dose vaccination numbers in this district.

...we ended up opting for data from [population-based] census as the [improvised] census has not given good information ... I think that the [improvised] census was too late and the lack of mobilization and also lack of funds created many problems. (Partner KII)

Finally, a third unintended consequence of the improvised census was that, as reported by some key informants, some community leaders who had not received financial remuneration (i.e., subsidies) for their role in conducting the census were actively discouraging the population from getting the vaccine.

... [community leaders] were promised subsidies and it is this subsidy that they were not paid... this generated controversy and led some of them [community leaders] holding the lists of the children and did not give them [to the census team], then there was a series of problems that I know of... this problem of paying these leaders was still not solved in Mocímboa da Praia, and this probably influenced the low coverage we had in Mocímboa da Praia, now we also knew that some children in Mocímboa da Praia ... did not go to school when they knew there was vaccination taking place, it is practically a refuse, in other words. (Partner KII)

Recommendations

- 1. The Gavi Secretariat and partners should provide technical guidelines for HPV demonstration project implementation that includes guidance on how demonstration activities relate to national roll out of HPV. Relatedly, in guidelines, the demonstrated ability criterion should be revised to more clearly emphasize demonstrated ability based on an average or representative site and conditional on development of a feasible delivery model for national introduction**

The main purpose of the demonstration project is to provide an opportunity for countries to gain “experience and evidence,” as described by a global-level key informant, which informs the decision of

whether or not to introduce HPV vaccine nationally and shapes and guides the plans for national introduction to ensure a smooth implementation. Our recommendation is that Gavi and partners more clearly emphasize this in relevant documentation including decision letters and implementation guidelines for the HPV vaccine demonstration projects.

Just as the requirement to demonstrate their ability to deliver HPV vaccine to 50% of the target cohort can incentivize countries to choose an “easy” district for the demonstration project, it may also influence design decisions related to planning and implementation, such as the decision to conduct a census to obtain a more accurate count of the target population. Although we do not have evidence to suggest that this is what drove Mozambique’s decision, we do think it important to point out the tension between gaining “experience” and gathering “evidence” to support national introduction. Because of the demonstrated coverage requirement, the incentive exists for countries to take steps to conduct a more robust demonstration project to ensure that they have evidence that they can achieve this target, and the risk of poor quality implementation if these activities are not feasible or not well planned.

To mitigate this risk, we recommend that the demonstrated ability criteria be modified as follows: “a country must have demonstrated ability to deliver a complete multi-dose series of vaccines to at least 50% of the target cohort using a process and delivery strategy or strategies which are feasible and similar to those proposed for national HPV vaccine delivery.”

2. Partners and Gavi should ensure that sufficient technical guidance (guidelines, tools, and also technical assistance) specific to HPV vaccine demonstration projects is available and accessible.

While many documents and tools are available to support demonstration and introduction of HPV, not all are specific to an HPV vaccine demonstration project, which has unique considerations for new vaccine introduction given the age of the target population and the primary learning objective. Further, some specific tools for HPV remain under development. It is also difficult for planners and implementers who are inexperienced with HPV to navigate all of these resources, especially as plans are often developed and/or revised rapidly and in concert with many other competing priorities. Ongoing technical assistance is needed during the demonstration phase, early and often throughout the process as plans are developed, refined and implemented, and to facilitate learning.

Robustness of finding

Finding	Ranking	Robustness Criteria
Insufficient technical guidance and underutilized technical assistance, coupled with the National Immunization Programme (NIP) and country-level partners’ limited knowledge on implementing HPV vaccine demonstration projects led to the unsuccessful implementation of a target population census in the HPV vaccine demonstration sites, which was ultimately abandoned. The resources required to conduct the census resulted in a lack of attention being paid to other preparatory	B	Findings were supported by data triangulated from KIIs, document review and meeting observation. The reason the census was conducted, however, was not clearly understood.

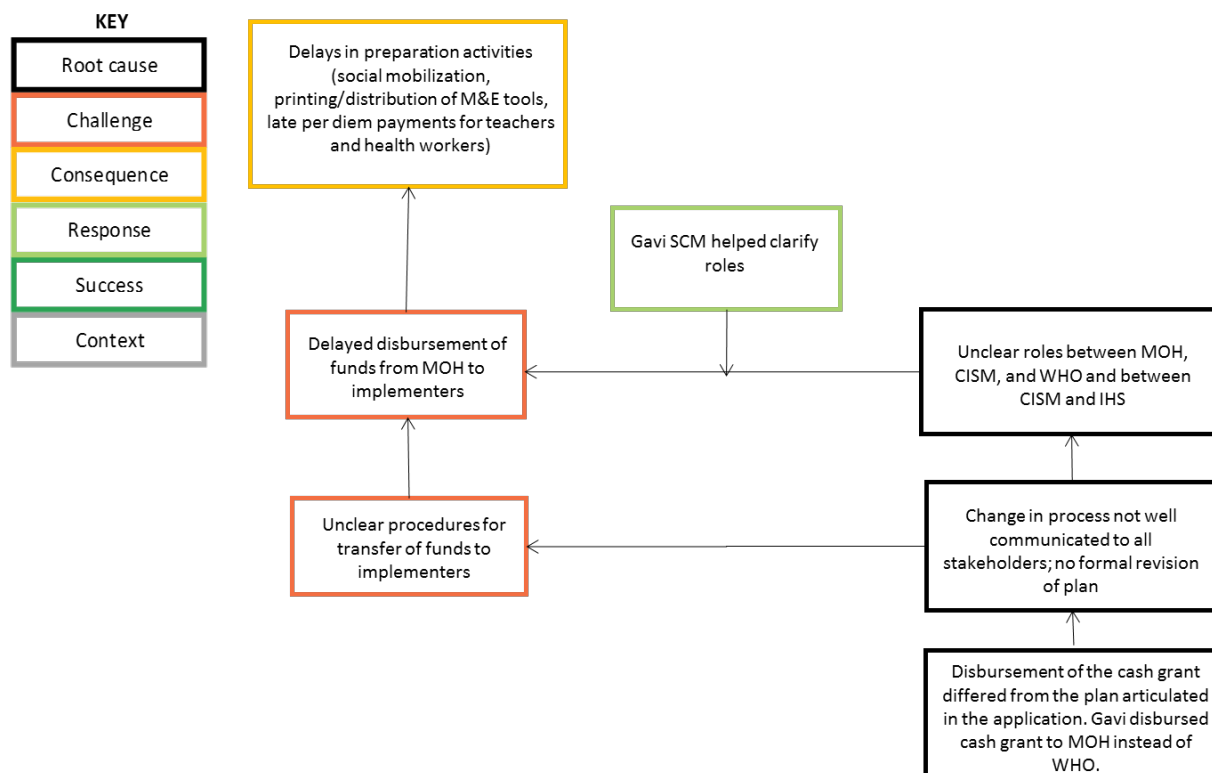
activities that affected the quality of the HPV demonstration project.

Finding 3

Funds were disbursed early from Gavi, in response to lessons from Mozambique’s experience with PCV. The disbursement entity, roles, and responsibilities of the NIP and partners however, changed, from what was stated in the approved application for the HPV vaccine demonstration project support in Mozambique. Even though these changes were positive because they better aligned with the purpose of the demonstration project, the changes were poorly communicated across all stakeholders and were not well planned. As a result there was confusion in roles and responsibilities and delayed in-country disbursement of funds to implementing agencies.

Several preparatory activities were delayed leading up to the launch of the first dose of HPV vaccine: social mobilization activities began only 10 days prior to the launch, printing and distribution of M&E tools to health facilities were not completed in time, and per diem payments to teachers and community leaders were delayed among others. In addition to the unplanned census, which diverted time and resources from these activities, another major contributing factor to the slow implementation was the delay in disbursement of funds from the MOH to implementing partners and the district level. In some cases, implementing agencies received funds only two weeks prior to the launch of the first dose. Figure 34 summarizes the root causes contributing to this delay.

Figure 34: Root cause analysis for delay in funds disbursement to implementing agencies



Two reasons for the delayed disbursement were: (1) confusion around roles and responsibilities among the key implementing agencies; and (2) unclear procedures for how funds were to be transferred from the MOH to implementing agencies.

Concern about the lack of clarity in roles was noted by the Independent Review Committee (IRC) in their review of the application.

The exact role of the Manhiça Foundation in the project is sometimes reversed with that of the EPI program – coordination or manager? This requires consistency in the proposal and will require clear understanding and communication to assure successful demo project. (p. 6, IRC report)

Key informants also indicated there was a continued lack of clarity during the preparation phase. For example, some KIIs mentioned a lack of clarity regarding WHO's role in provision of technical assistance. In the application, WHO had been designated to receive funds and when funds were disbursed to MOH; this created confusion. Also when the two government districts were included it was at first not clear whether CISM was also expected to evaluate these two new districts or if National Institute of Health (INS) would evaluate the demonstration project. In fact, it wasn't until the Gavi Senior Country Manager (SCM) visited the country in March 2014 that roles were clarified. This clarification indicated that the MOH was to implement, WHO was to provide technical assistance, as they had traditionally done for vaccine introductions, CISM was to evaluate the demo project in Manhiça district, as stated in the application, and INS was to evaluate in Manica and Mocimboa da Praia.

Even after roles were clarified, disbursements were further delayed because it took time to transfer funds. The procedures that needed to be followed to request and then process the funds were unclear.

[The head of the NIP] announced that partners who require funding had to submit a letter of request to the Ministry...it then took me some time to know to whom I should submit the letter and what should be in the content of letter, then [another partner] said...do not worry we'll do our letter and we will show it to you, as we have done before....then only when [our role] was made really clear..., that's when we asked [the other partner] to give us the template for the letter, and we...prepared the letter and I do not know how many weeks it took to carry over... (Health partner KII)

A major factor underlying the confusion in roles and procedures was a change to the process which had been proposed and approved in the application for the demonstration project. According to the grant application, funds were to be channeled to CISM (at that time designated as project manager) via WHO and detailed procedures were outlined for how these transfers were to occur. However, after the application was approved, the cash grant for preparation was transferred to the government. This change was not sufficiently communicated to all stakeholders.

... The problem was first communication and then was lack of clarity in the application guidelines ... we said what we wanted but then at the time of implementation, it was something else, then when we asked for clarification and we got something else, for example the during the application [Gavi] did not encourage the MOH to receive money directly, it encourages more trusted partners such as UNICEF or WHO to receive the money and then they would support the Ministry in managing money because of the antecedents the ministry had regarding the

mismanagement of Gavi money, but when the funds arrived we were surprised to know that the funds were directly disbursed to the Ministry. (Health partner KII)

The funds transfer to the government instead of via WHO, as was originally planned, appears to be the result of a request made by the MOH to Gavi. After the application was approved, in a series of correspondence between the Gavi Secretariat and the MOH, plans were set forth and enacted to disburse the cash grant to the MOH's account. The request was prompted by the country's experience in the PCV introduction, where the VIG arrived in country only two weeks prior to the launch and was routed through UNICEF and WHO, which retained part of the funds to support the cost of administration.

We reacted after the introduction of PCV, because the money was disbursed to WHO and UNICEF, and there were difficulties in the management and the money arrived late, still it was retained for administrative procedures at the source (WHO and UNICEF). Then [MOH] complained...but also Gavi itself always said that the management of funds are the government's responsibility and encouraged us to receive [the funds]. So after approval when they asked us how we wanted the funds, we said we want it to be disbursed [for implementation] through the MOH. (MOH KII)

It is important to note that this shift in disbursement entities is more aligned with the intent of the HPV vaccine demonstration projects that countries implement, learn and prepare for national introduction. Our assessment is that this change was positive and aligned with Gavi's principles and priorities as well as the needs and priorities of the country.

It is clear that main Vaccine Alliance partners (WHO and UNICEF) were aware of the change in plans for funds disbursement, but it is not clear when or if other implementing agencies were made aware. There was certainly no formal revision of the plans outlined in the application. The lack of broad communication in the changes to these plans and lack of formal approval to the changes likely contributed to the confusion of roles and responsibilities. Moreover, because there was no formal process for revising the plans, some details such as procedures of funds disbursement from MOH to implementing partners were not fully considered.

Recommendations

- 1. The Gavi Secretariat should establish a formalized process for changes to implementation plans that occur after approval, including changes in designated roles and funding recipients. Country governments, country-level partners and the Gavi Secretariat should ensure that changes in these roles are communicated to all relevant parties.**

As we note in our analysis, the change in roles and responsibilities from those specified in the application to ensure that the NIP was the leading implementation agency resulted in better alignment with the purpose of the demonstration project and the principle of country ownership. MOH will ultimately lead national introduction efforts so demonstration projects provide an opportunity for them to learn about the challenges of this particular new vaccine introduction. The main challenge observed was not the change in roles per se but that there was a lack of clarity and communication about the changes. As the roles and responsibilities of different institutions is critical in the implementation of Gavi support, and especially in the case of HPV vaccine as a broader set of partners is engaged, we

recommend that a more formalized process is implemented to document changes to them that occur after the approval of Gavi support. This would also help facilitate the second part of our recommendation, which is that country governments, country-level partners and the Gavi Secretariat ensure that changes in these roles are communicated to all relevant parties.

2. Gavi should continue to ensure that the leading implementer for demonstration is the MOH if they will be the main implementer for national introduction.

As noted under the previous recommendation, given that country governments will be the main implementer for national introductions, Gavi and partners should ensure that they are also the leading implementer for demonstration projects.

Robustness of finding

Finding	Ranking	Robustness Criteria
Funds were disbursed early from Gavi, in response to lessons from Mozambique's experience with PCV. The disbursement entity, roles, and responsibilities of the NIP and partners however, changed, from what was stated in the approved application for the HPV vaccine demonstration project support in Mozambique. Even though these changes were positive because they better aligned with the purpose of the demonstration project, the changes were poorly communicated across all stakeholders and were not well planned. As a result there was confusion in roles and responsibilities and delayed in-country disbursement of funds to implementing agencies.	A	Findings were supported by data triangulated from KIIs, document review and meeting observation.

Health system strengthening

Summary of Progress

Mozambique submitted two unsuccessful applications (2009 and 2012) for Health system strengthening (HSS) support from Gavi prior to a visit by Gavi CEO Seth Berkley in March 2012. According to fact-checking interviews, HSS support for Mozambique was an important priority for the CEO upon his return from the country. After substantial revisions, Mozambique's third HSS application was approved in August of 2013.

Mozambique's health system, although dramatically improved since the signing of the Peace Accords in 1992, has been considerably challenged by significant rates of HIV/AIDS, malaria and tuberculosis, as well as vaccine preventable diseases. Underpinning these health system challenges are limited and weak human resources, fragile logistical systems, and the systematic underdevelopment of effective and appropriate monitoring and evaluation systems. These core building blocks of the health system are

critical to ensuring that the massive investments entering the country through initiatives like Gavi's are effectively used to improve the health of Mozambique's population. In the successful HSS application, Mozambique identified the following critical bottlenecks in the health system that were affecting immunization service delivery:

- Persistence of logistics and supply chain management bottlenecks;
- Poor data quality management;
- Poor management of health services at district level and below;
- Lack of human resources, insufficient staff training, and inadequate technical supportive supervision of staff at all levels;
- Inadequate health financing for the entire sector; and
- Limited outreach activities for delivery of priority health services due to limited HRH and transportation, leading to weak community participation on health service delivery.

In response to these bottlenecks, the design of the HSS program presented in the application consists of five objectives:

1. To achieve equitable access to routine immunization services through sustained investment in service delivery throughout the health system and at the community level;
2. To increase the availability and efficiency of immunization services through the improvement of the immunization supply and logistic system;
3. To sustain quality, humanity, motivation and accountability of the health workforce along the whole immunization chain;
4. To strengthen the health information system and the EPI data management for decision making; and
5. To promote an enabling environment and political priority for immunization services through effective advocacy, communication and social mobilization.

The operational plan to address these five objectives allocated the five-year US\$25 million grant across activities organized into four core areas: strengthened human resources for health, recurrent costs and infrastructure, training and capacity building, and community outreach. Table 20 summarizes the progress and successes, as well as challenges and responses, associated with the process of implementing the approved HSS support for Mozambique.

Table 20: Summary of country progress

Milestone heading	
Critical bottlenecks to immunization coverage are identified	
<ul style="list-style-type: none"> - Based on document review, the assessment of bottlenecks presented in the application was evidence-based. Each bottleneck was linked to findings reported in the post-introduction evaluation of Hib, the effective vaccine management assessment (EVMA), data quality audit, and various planning and strategy documents including the cMYP and HRH 2008-2015 plan for Mozambique. Indicators from Demographic and Health Survey and other surveys, and grey literature mostly developed by NGOs are also cited. - According to the application, there was strong involvement of key partners (ICC) in the identification of critical bottlenecks. In subsequent meetings attended by FCE team members, these critical bottlenecks were consistently referenced, especially the cold-chain challenges and the human resources for health (HRH) shortage at all levels of the health system. 	
Appropriate responses to address bottlenecks are identified/developed	
<ul style="list-style-type: none"> - The responses are not justified in the application with specific evidence <i>per se</i>, although they encompass priority activities which have been included in existing strategic plans (for example some activities surrounding HRH came from the HRH 2008-2015 strategic plan). - The responses are logically linked to the bottlenecks; they acknowledge a systems-level view of the problem and address the various building blocks necessary to achieve effective and sustainable Health system strengthening. 	<ul style="list-style-type: none"> - The proposed responses to the bottlenecks lack prioritization which would more effectively allow the country to phase-in the proposed efforts. Given the human resource challenges in the country, specifically in management at all levels, the proposal is challenging to operationalize.
Comprehensive and complete Gavi HSS funding application submitted in time, and sufficient amount of Gavi funding secured	

Milestone heading	
<ul style="list-style-type: none"> - There was considerable support from key partners to complete the application (e.g., WHO, UNICEF, and Village Reach). - The HSS application was conditionally approved by Gavi in August 2013 after two unsuccessful attempts. - Gavi required a full operational and procurement plan prior to disbursement of funds. 	<ul style="list-style-type: none"> - Initially the MOH assumed they would be required to submit one operational plan; however, they were required to submit three plans (M&E, operational plan, and procurement).
Plans adequately updated for implementation	
<ul style="list-style-type: none"> - The operational allocations were developed by the immunization TWG and approved by the ICC in May 2014. - A full operational and procurement plan was submitted on September 15, 2014. - On November 10, 2014, Gavi requested that Mozambique clarify and revise a few issues in the plans submitted. - The country responded with a revised set of plans which were received and accepted on November 25, 2014. 	<ul style="list-style-type: none"> - Work on development of the operational and procurement plan slowed when NIP management changed in Feb 2014. - There was turnover at both the NIP manager and Gavi Senior Country Manager (SCM) positions, which led to delays in submission of the required plans by the country. - Language remained a barrier for communication between the NIP and Gavi Secretariat. - Despite the fact that the Partnership Framework Agreement signed between Gavi and the Country (December 6, 2013) stated that Gavi funds shall not be used to cover customs costs for importation of vaccines, there was ongoing confusion around who would cover customs costs for vaccines. - The HSS plan did bring in priorities of existing plans-such as those detailed in the 2008-2015 HRH strategy. However this link is not made explicit in in the operational plan. - It is unclear how the community outreach activities will be linked to the other activities (via CBOs, NGOs or state institutions such as social welfare).

Analysis of major challenges and successes

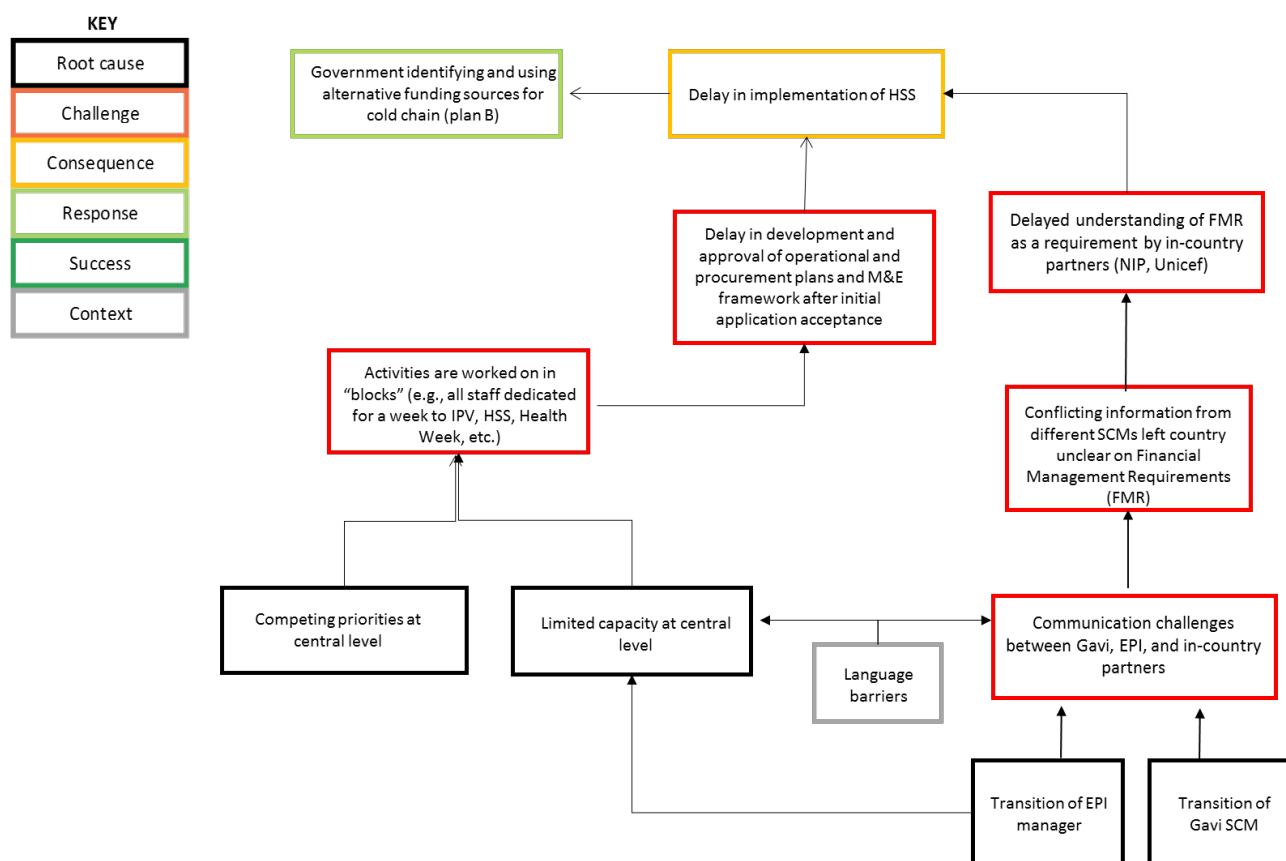
Finding 1

Communication challenges between the NIP and Gavi Secretariat, coupled with competing priorities and staff turnover at NIP and Gavi, led to submission delays in the development of key Gavi HSS

conditionalities (Year 1 OP and Monitoring and Evaluation [M&E] framework) and the start-up of HSS support in Mozambique.

The primary challenge that the Gavi FCE identified in the HSS funding stream was the long delay between the start of the HSS support stream following the approval of the application. It has taken over a year for the NIP to successfully respond to Gavi’s data requests, which included an amended monitoring and evaluation framework, a procurement plan and an operational plan and budget for year one of this five year funding stream. A number of key root causes for this delayed implementation are shown in Figure 35.

Figure 35: Root cause analysis for delayed implementation of HSS



Our findings suggest several root causes of the delay in implementation of the HSS grant. First, implementation was hampered because of competing priorities at the central level. Competing priorities included previously planned activities related to the HPV vaccine demonstration project (as identified by the IRC) and also new support streams, most notably IPV, which the Vaccine Alliance opened at the end

of 2013. Interviews with key partners suggest that the development and submission of the IPV proposal was also given priority over HSS, and further delayed the necessary responses to Gavi to allow the implementation of HSS to proceed. To a certain extent, the complexity of the HSS proposal encouraged the NIP to finish other, more well-defined, tasks, such as the development of the IPV proposal and implementation of HPV vaccine.

Another root cause was limited human resource capacity at the central level within the NIP to carry out EPI activities. With a small team of 12 officers (one NIP manager, one M&E officer, four logistics officers, five maintenance officers, and one training and communication officer), the NIP resorts to carrying out work in blocks, with specific weeks dedicated to certain streams of implementation (e.g., HPV vaccine demonstration project, National Health Week, and PCV). Moreover, limited capacity of NIP during this period was compounded by the turnover of the NIP manager in February 2014. Although partners provided support in a unified fashion through the immunization TWG to help off-load certain tasks, ultimately the NIP was constrained to focusing on only one major activity at a time.

Limited capacity and competing priorities together resulted in a protracted period (from January to September 2014) of drafting and revising M&E Framework as well as the Annual Workplan and Budget (AWPB) and the procurement plan, which were conditionalities of the Financial Management Assessment (FMA) conducted in April 2013. In addition, all documents and communication had to be submitted in English, which also posed challenges for the NIP, as previously noted in our 2013 evaluation of PCV introduction. Notably, the challenge of limited management capacity was well recognized; for example, the IRC review of the first HPV vaccine application had flagged it and recommended that the government prioritize implementation of the HSS.

Also contributing to the slowed implementation were communication challenges between the NIP and Gavi Secretariat, stemming from the transition of both the NIP manager and the Gavi SCM in 2014. NIP and UNICEF indicated that, during this period, they received mixed messages about the financial management agreement process, including the signing of the Financial Management Requirements (FMR), which left the country unclear on how to move forward with implementation. After the approval of the operation and procurement plans and M&E Framework in September 2014, it took another three months before the NIP received the FMR from the Gavi secretariat in December.

As monies related to HSS were not available, the NIP accepted alternative funding for cold chain support that was offered by USAID. Expansion of cold chain capacity was essential to prepare for new immunization streams, including rotavirus, measles second dose, and IPV scheduled to be introduced in 2015. The cold chain equipment was purchased in July and October of 2014. The downstream effect of this shift in funding source was the necessity to rework the HSS budget, which further contributed to the delay in finalizing the procurement and operational plan for year one HSS.

Recommendations

- 1. In countries with limited central capacity and/or other important implementation bottlenecks, country governments, partners, and Gavi should more carefully consider whether implementing multiple support streams is feasible. For Mozambique, this extends to a reassessment of the feasibility of current plans to introduce rotavirus vaccine, measles second dose vaccine, and IPV in 2015 alongside the ongoing implementation of the HPV vaccine demonstration project and the expected start-up of HSS.***

The HSS findings highlight the challenges that NIPs face when attempting to implement multiple Gavi support streams, particularly in low-resourced, fluctuating settings like Mozambique. It also highlights how generally, HSS efforts can often be postponed, delayed, and under-prioritized when other more immediate and easily implementable activities are jockeying for attention (we also observed this in Bangladesh). Our findings suggest, for example, that the work required to develop and submit an application for IPV contributed to the delays in developing adequate responses to initiate the HSS funding stream (the M&E framework, procurement and implementation plans). Notably, the concern about the NIPs ability to manage multiple streams of support, i.e. HPV vaccine and HSS, was previously flagged by the IRC prior to the decision to apply for IPV support. We recommend that countries, partners, and the Gavi Secretariat examine more comprehensively the feasibility of implementing multiple support streams throughout the decision-making, application and approval phases. This is discussed further in the cross-country analysis section.

More specifically, while globally based initiatives such as the Global Polio Eradication Initiative may be justified and agreed upon for prioritized implementation; countries, partners and Gavi should consider how implementation of previously unplanned initiatives may impact other support on a case-by-case basis. This includes revising implementation and introduction timelines to meet country level priorities. For Mozambique, this recommendation is relevant to 2015, where the current plans involve the introduction of multiple new vaccines (rotavirus vaccine, measles second dose vaccine, IPV) alongside ongoing implementation of the HPV vaccine demonstration project and the hopeful start-up of HSS activities.

2. Country governments, partners, and Gavi should consider strengthening central capacity and additional technical support to allow countries to manage and implement multiple support streams. This could be implemented through the existing HSS support stream.

One clear bottleneck highlighted by this analysis is the limited central capacity to manage the various phases of Vaccine Alliance support. We recommend that country governments, partners, and Gavi consider steps to strengthen central capacity to implement Gavi support. Mozambique has allocated in its HSS plan some support for strengthening of central capacity through the establishment of a Programme Coordination Unit and additional human resources for M&E and human resource training. Central capacity strengthening can take time to achieve; in the meantime we recommend that enhanced, consistent technical assistance be provided to countries such as Mozambique that are expected to implement multiple streams of support over a limited time frame. This technical assistance could be supported through seconded advisors in the NIP. We will continue to explore the structure and performance of the partnership network in Mozambique.

3. Gavi should improve communication by jointly developing explicit communication norms, roles and expectations of NIP/MOH managers, key Alliance partners (e.g. UNICEF, WHO), and the Gavi Secretariat, through written and mutually agreed upon terms of references. This should include alternate designees to limit the problem of staff turnover.

Our analysis highlights the contribution of communication challenges as a contributing factor to the delayed implementation of HSS. While human resource turnover at both country and Secretariat levels are inevitable, strategies to mitigate them, like clear, transparent communication norms and statements of work, are essential. We recommend that written communication protocols should be developed to help mitigate the effects of turnover and provide clarity for the responsible parties, especially in

countries that speaks a language not generally spoken at the Gavi Secretariat. Such protocols will help newly appointed individuals adapt to their roles in the Vaccine Alliance more quickly and ease concerns at the country level. We recommend that alternative designees be specified in the protocols to limit the problems that arise from human resource transition periods.

Robustness of findings

Finding	Robustness Ranking	Robustness Explanation
Communication challenges between the NIP and Gavi Secretariat, coupled with competing priorities and staff turnover at NIP and Gavi, led to submission delays in the development of key Gavi HSS conditionalities (Year 1 Operational Plan and M&E framework) and the start-up of HSS support in Mozambique.	B	Data was supported by data triangulated from document review, observation and fact checking interviews. Formal KIIs have yet to be conducted.

Pneumococcal conjugate vaccine

Summary of progress

Mozambique introduced the 10-valent pneumococcal conjugate vaccine (PCV) as part of its routine immunization program in April 2013 with support from Gavi. The introduction consisted of a nationwide launch that included all health facilities providing immunization services. The 2013 Annual Report included specific details on the launch and immediate sequelae. During 2014, the FCE team targeted its evaluation on PCV's integration into the routine system. In the Theory of Change that guides the PCV introduction, this milestone is referred to as *routinization*. PCV routinization is defined as administering as many doses of PCV as other existing, routine vaccines. Table 21 includes the main findings on progress of routinization as well as successes and challenges noted.

Table 21: Summary of country progress

Milestone heading	
Successful launch of PCV	
<ul style="list-style-type: none"> - The initial month of reporting PCV to the HMIS varied by district and province. - NIP relied on a parallel system, where district NIP officers compiled data from the paper forms to excel spreadsheets to report to the national level. 	<ul style="list-style-type: none"> - It is difficult to differentiate between reporting PCV and actually administering PCV with HMIS. - Although NIP M&E tools were updated before the launch, they did not arrive in health facilities until two to three months after the launch.
<ul style="list-style-type: none"> - The PCV PIE was conducted in November 2013. - At a NIP retreat in April, PIE recommendations were discussed and an action plan was made to remedy multiple challenges; M&E tool printing and distribution was also highlighted. 	<ul style="list-style-type: none"> - PCV data were not reliably reported in the HMIS Módulo Básico until December 2013. KIIs from 2013 informed that there were numerous modified reporting techniques-most were not captured by the routine HMIS.
Routinization of PCV	

Milestone heading	
<ul style="list-style-type: none"> - Administrative reporting systems observed nearly as many doses of PCV administered as pentavalent by July 2013. - The ratio of third doses of PCV reported to third doses of pentavalent reported increased each month to approximately 0.93 by December 2013 (Figure 36) indicating that PCV routinization progressed over time, but was not complete by December. - Using estimates from the HMIS, the coverage of PCV vaccination varied by province and district, ranging from zero to greater than one, reflecting reporting issues and denominator issues (Figure 37). - The percentage of districts and percentage of health facilities reporting PCV to the HMIS increased nearly every month from April 2013 to February 2014, and were last observed at 92% and 81% respectively. The outlier was Manica province and fact-checking information regarding this province is outstanding. 	<ul style="list-style-type: none"> - The NIP used a parallel based reporting system for PCV, which varied in format and comprehensiveness by province. - In total, NIP parallel reporting system counted more PCV doses administered in 2013 than the HMIS, but was not available for every month in every province, therefore supplementing it with HMIS data was necessary when possible (Figure 38). - Coverage estimates for PCV are difficult to interpret due to poor/changing data quality in the denominator and selective challenges with form availability (Table 22).

Launch

Mozambique introduced the 10-valent PCV into its routine immunization program in April 2013 with support from Gavi. One of the major challenges faced during the PCV introduction was the delay in rolling out the updated NIP M&E tools. The tools were updated before the launch but there were delays in printing and dissemination to health facilities. During the 2013 evaluation period, the FCE team found out that health facilities did not receive updated tools until two to three months after the launch. When the PIE was conducted after six months, health facilities had still not received the updated tally sheet.

Further delay was also observed in the inclusion of PCV data in the electronic HMIS, where PCV data was not entered reliably until the end of 2013. During this period, NIP relied on a parallel system, where district NIP officers compiled data from paper forms to excel spreadsheets to report to the national level. This was the “official” source of data used by the NIP until the end of 2013. Provinces transitioned to reporting through the HMIS at varying times though, so PCV data that are included in either database for the year 2013 are incomplete. The result is that the most complete data about PCV is a combination of the two.

Routinization

The national PCV-to-pentavalent ratios in Figure 36 demonstrate that while PCV routinization has progressed, it was not complete as of December 2013. Figure 36 reflects data from the NIP parallel

reporting system with data from the HMIS used to supplement missing provinces and months. The increasing trend is influenced by increasing amounts of PCV administered and increasing reporting of PCV to the HMIS and NIP systems. Figure 36 shows progress in routinizing PCV by province. It also demonstrates issues with data quality among the NIP and HMIS reporting systems, as missing values are present between both. From these graphs, it is clear that most provinces had reached, or had nearly reached complete routinization (1:1 ratio with pentavalent) by December 2013. Manica and Sofala had data in neither the HMIS nor NIP reporting system in certain months resulting in trends that are difficult to interpret.

The maps in Figure 37 show the PCV-to-pentavalent ratio (according to data from both reporting systems) at the district level at four specific months: April, July, October and December 2013 (all months from April 2013 to December 2013 can be found in Annex 9). District-level routinization of PCV generally followed provincial findings, with some districts starting earlier or later than others within provinces. Many districts reported more PCV doses administered than pentavalent, indicating a period of “catch up.” As of February 2014, 137 districts (92%) were reporting PCV to the HMIS, up from 21 (14%) in April 2013. Table 22 shows the number of health facilities reporting PCV to HMIS in each month.

Coverage

According to the HMIS data, national coverage of the third dose of PCV reached 83.6% by February 2014.

Figure 39 shows district-level PCV third-dose coverage in February 2014, as computed by HMIS data. A number of factors make coverage based on HMIS data challenging to interpret. The largest challenge among them is uncertainty related to the denominator (health facility target for PCV) followed by incomplete reporting from all facilities, as described in Table 22. Many anomalies are clear from the map, including a number of districts with coverage greater than 100% and many with a coverage of zero. This indicates that alternative sources of data are required, at least to supplement HMIS and the NIP parallel system, to accurately estimate PCV coverage.

Figure 36: National PCV-to-pentavalent ratio, based on the NIP parallel reporting system and HMIS

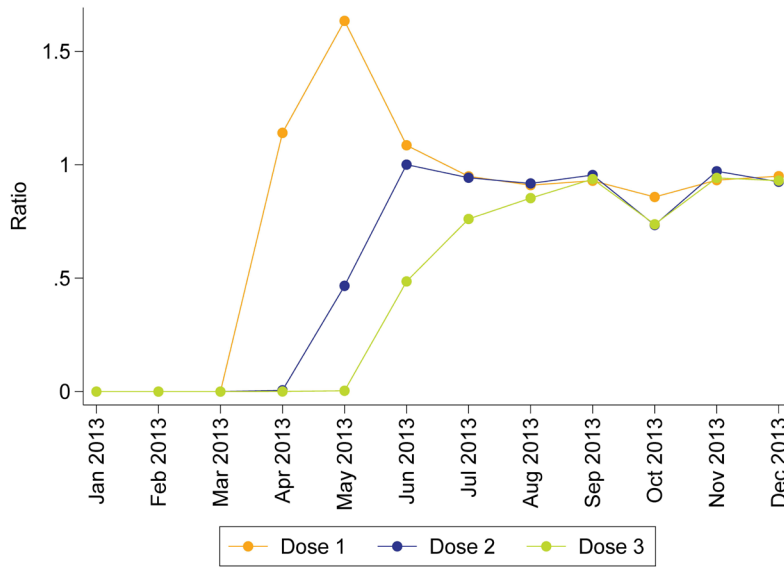


Figure 37: PCV coverage (third dose) computed from HMIS, February 2014 (percent)

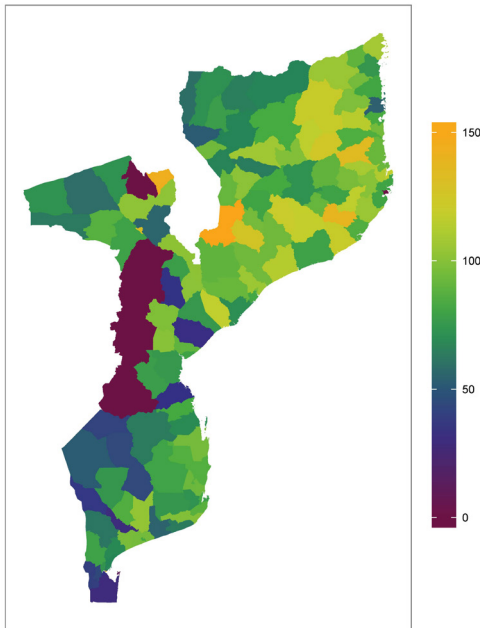


Figure 38: PCV-to-pentavalent ratio by province, with and without supplemental HMIS data

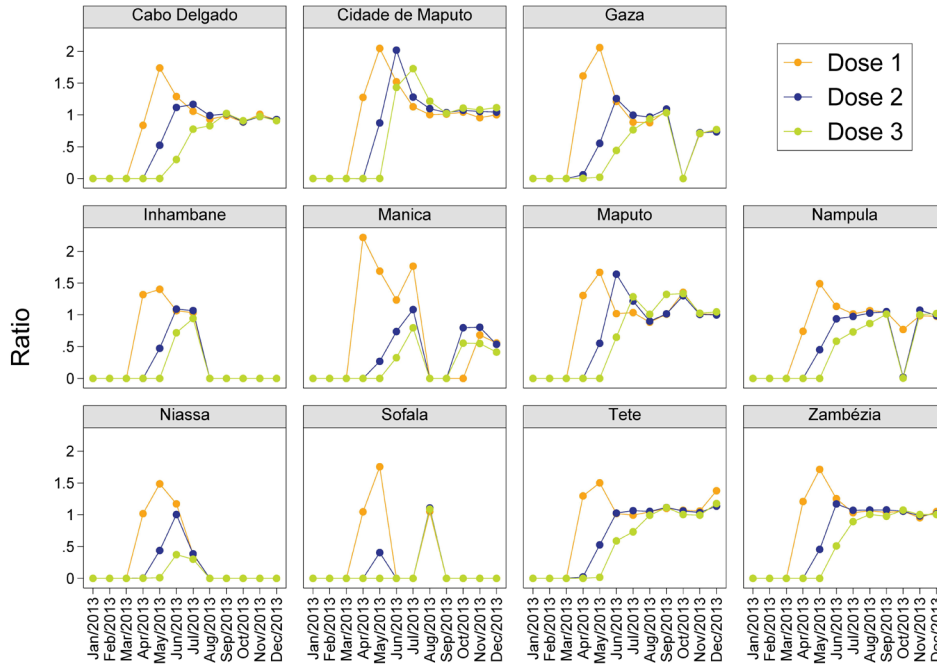


Figure 39: Mozambique PCV-to-pentavalent ratio, district level based on the NIP parallel reporting system and HMIS

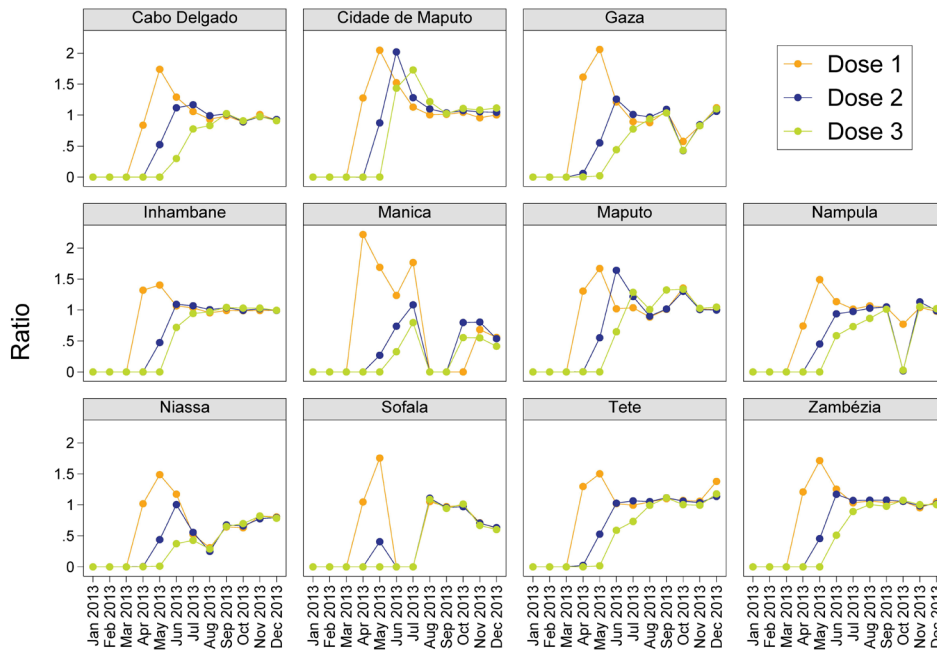


Figure 40: PCV to pentavalent ratio by district with supplemental HMIS data

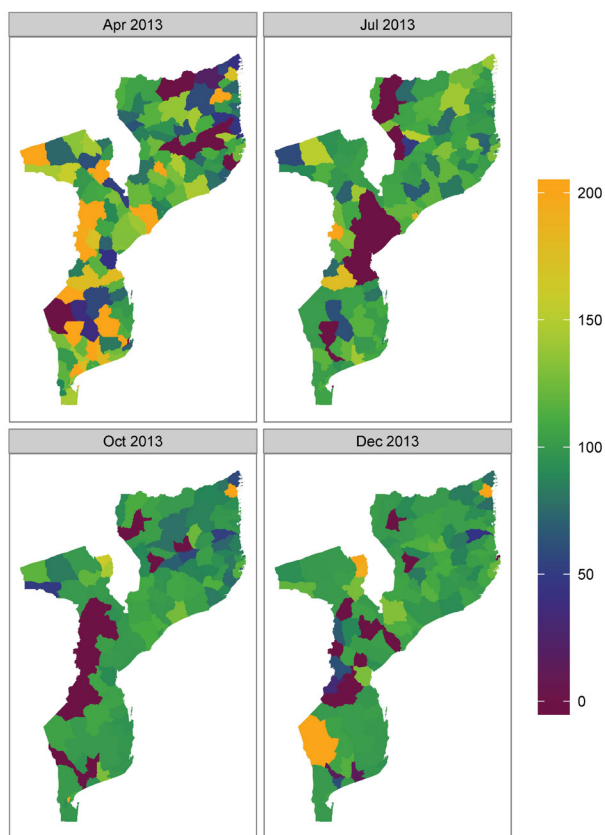


Table 22: Number of health facilities reporting PCV to HMIS by month

Date	Health facilities reporting at least one PCV dose administered	Total health facilities reporting vaccine data to HMIS	Percent
Apr 13	98	1251	7.8
May 13	109	1268	8.6
Jun 13	187	1248	15.0
Jul 13	46	1245	3.7
Aug 13	392	1259	31.1
Sep 13	655	1263	51.9
Oct 13	745	1246	59.8
Nov 13	873	1245	70.1
Dec 13	872	1251	69.7
Jan 14	1012	1243	81.4
Feb 14	1022	1256	81.4

Inactivated polio vaccine

Summary of progress

In 2014, Mozambique applied for Gavi support for IPV with an introduction date set for 2015. The application took advantage of the decision by the Gavi Board in 2013 to support the introduction of IPV as part of routine immunization programs. Gavi support for IPV introduction waives a number of application criteria, including co-financing; however, countries must apply for support by June 2015 with introduction targeted by the end of 2015. Though the FCE has been tracking the application process, we have yet not undertaken in-depth process evaluation of this stream.

Based on information provided by key officials, a preliminary work plan facilitated the application development process, and the necessary information for the application was collected without any noted limitations. The proposal writing group was composed of the three main key stakeholders NIP, WHO, and UNICEF. The ICC, led by the Mozambique National Director of Public Health and including Village reach and FDC (the other key NIP stakeholders in country), reviewed and endorsed the application proposal before submission. Technical assistance on the IPV application was provided by the WHO AFRO regional meeting at the end of June 2014; the aim of this meeting was to guide countries in the IPV proposal development process.

The IPV application was submitted on September 15, 2014. The FCE team will continue to track progress on this stream in the coming years.

A notable negative unintended consequence of the global push for IPV introductions was the delayed disbursement of HSS funds. With the increased priority of IPV applications, the introduction deadline of the end of 2015, and the limited central capacity of the NIP prioritized the IPV application process, HSS activities were not implemented as planned.

Rotavirus vaccine and measles second dose

Summary of Progress

The first combined rotavirus vaccine and measles second dose (MSD) application was submitted to Gavi in August 2012. Gavi responded in November 2012 that due to a number of weaknesses including contradictory cold-chain information, no information on disease burden in country or the region, targets that were not in keeping with country performance, and numerous incorrect references to PCV instead of rotavirus vaccine in the application document, the application was not approved. The country was requested to resubmit another application addressing some of the issues raised by the IRC and a new application was submitted in January 2014 proposing introduction in 2015. This application was subsequently approved. A detailed plan for a nationwide simultaneous introduction of the two vaccines was submitted with the application. As part of the decision making process in country, in June 2013 during the preparation phase of the second rotavirus vaccine and MSD application the NIP TWG developed a position statement for presentation in ICC and other senior decision making levels at the MOH. It was a six page document that compared the implications of choosing Rotarix versus Rotateq on the cold-chain system in Mozambique and proposing Rotarix whose requirements for the expansion of the cold-chain would be less as compared to the requirements for Rotateq vaccine. Currently no rotavirus vaccine MSD launch preparation specific activities are taking place at NIP central level.

Table 23: Proposed immunization schedule

Immunization for infants			Immunization for pregnant women and women of childbearing age		
Age	Visit	Antigen	Visit	Interval	Antigen
Birth	1	BCG, OPV0	1	0 (as earlier as possible)	TT1
6 weeks	2	DPT-HepB-Hib1, OPV1, Rota 1	2	Four weeks after first dose	TT2
10 weeks	3	DPT-HepB-Hib2, OPV2, Rota 2	3	Six months after second dose	TT3
14 weeks	4	DPT-HepB-Hib3, OPV3	4	One year after third dose	TT4
9 months	5	Measles first dose	5	One year after fourth dose	TT5
18 months	6	Measles second dose			

Cross-stream findings for Mozambique

Based on our analysis across the various streams of Vaccine Alliance support, a number of common themes emerged as discussed in further depth here.

Limited central capacity and competing priorities in the context of multiple support streams
The central NIP team consists of twelve key personnel who are responsible for managing all NIP activities, including policy definition, determining standards and priorities, coordinating with partners, mobilizing resources, procurement and supply management of vaccines and other NIP products, program monitoring and evaluation, as well as capacity building in provinces through providing technical support. This is in addition to all new streams of funding from Gavi. Planning and realistic timelines for Gavi support are a challenge for Mozambique in the context of multiple support streams are coupled with the limited management capacity of the NIP. This was apparent during the 2014 evaluation period when the NIP was unable to fulfill its plans to launch two new streams of funding (HPV vaccine and HSS) in parallel to the management of a new application for IPV. Some streams were prioritized at the expense of others; in this case, the HPV vaccine demonstration project and the IPV application were prioritized over the HSS. In the context of the challenges faced with implementing multiple support streams in 2014, we strongly recommend a reassessment of the timeline for 2015, given the current plan to introduce three new vaccines alongside ongoing streams of support.

An emerging theme related to capacity is centralized planning. One of the PCV PIE recommendations was that subnational introduction plans should be developed early in the launch preparation phase. During 2014, the subnational levels were involved only one week prior to the launch, with consequences met during the initial implementation phase of the first dose of the HPV vaccine demonstration project. A lack of sub national level introduction plans was observed too. This is an area for the FCE team to investigate further in the 2015 coming evaluation period.

Suboptimal communication between the NIP, country-level partners and Gavi Secretariat
Across Gavi streams of support in Mozambique we identified critical challenges in the communication between the NIP, country-level partners, and the Gavi Secretariat. These challenges led to delays and rushed implementation. For HSS, communication challenges and delays contributed to the delays in the development and the submission of the M&E framework, procurement, and implementation plan.

When queried, several global level key informants described the primary modes of direct communication between the country and the Secretariat to include email, in-country visits, and formal correspondence (information letters, decision letters, APRs, applications, high level review panels, etc.). Teleconference calls directly with counterparts in the MOH were not mentioned by any of the global-level KIIs.

These communication challenges occurred within a context of position turnover with both the NIP manager and SCM. As we recommended, measures are required to limit communication gaps that result from this turnover. In the case of the SCM, avoiding high levels of turnover – two changes in a single year – would also reduce the potential for communication challenges. We also note that the SCM transition was not formally communicated, according to one global key informant, “as far as I know, [the transition in SCM for Mozambique] was not formally communicated [by the Secretariat to the country].”

Partner engagement and technical assistance

The FCE 2013 report on PCV introduction noted the strength of the stakeholder partnership at the central level. However, this result is tempered somewhat by our findings in Mozambique in 2014. For HPV vaccine, while one MOH KII noted the key role of technical assistance “provided by the Gavi Secretariat through a consultant” to assist with the development of the demonstrational application, the same key informant also highlighted the lack of the clear guidance on HPV vaccine introduction from WHO (for example, it was pointed out that no vaccine introduction manual for HPV vaccine was developed or shared).

Another example of challenges with partner engagement and technical assistance emerged from interviews with global level key informants. One partner assigned to provide support to Mozambique noted that repeated attempts to offer assistance for planning and preparation for HPV vaccine delivery in Mozambique went unanswered for over six months. With less than two weeks prior to delivery of the third dose, the MOH finally reached out to request last minute support for the PIE. The reason for the delay was perceived to be an issue of trust, or lack thereof, for this new partner. As noted in the HPV vaccine section of this report, one consequence of incomplete guidance, including technical assistance, was an ineffective effort to conduct a census which was ultimately determined not to be appropriate. Further investigation of underlying barriers to effective partnership and provision of technical assistance is warranted.

All of these emerging themes on competing priorities, communication, central planning, and partnership are quite informative for the planning of FCE 2015 activities in Mozambique which will include a more systematic assessment of partnership and further tracking of HSS and the multiple new vaccine introductions which are planned. In addition, a more in depth contingency study is being conducted to describe the experiences of HPV vaccine demonstration projects in non-Gavi sites, and in particular the added value of synergizing with one Gavi-supported site.

Conclusions

Overall Gavi support to introduce new vaccines in Mozambique has been beneficial and generally well-administered. In the last two years, Gavi has supported national introduction of PCV, which appears to be largely routinized in the routine EPI system. The HPV vaccine demonstration project, supported by Gavi in one district, is contributing to learnings for eventual national HPV vaccine introduction. It is likely that the addition of these new vaccines in this time period without Gavi support. With the HSS grant,

although delayed, the NIP and partners will begin to implement a range of system strengthening activities with the aim to increase coverage, reduce inequity as well as support future new vaccine introductions.

There are, however, a number of challenges noted in the evaluation. First, communication must be strengthened in order to ensure that Gavi Secretariat, partners, the MOH, and other stakeholders are able to optimally coordinate their efforts and best utilize the resources dedicated to immunization services in the country. Communication norms between the Gavi Secretariat and the MOH and partners (such as in-country UNICEF and WHO) are not clear to all parties, and as a result the actions are not always widely disseminated when decisions are made at any level. Communication is also hampered by a lack of clarity and consensus on roles and responsibilities pertaining to Gavi-supported activities. In particular, the Gavi Business Plan and the roles of UNICEF and WHO as the technical partners of Gavi are not universally understood by all Mozambican stakeholders, further muddling decision-making and generally slowing down efforts. These communication challenges are exacerbated by turnover of key staff at both the Gavi Secretariat and at the MOH, and also by the lack of Gavi Secretariat personnel with Portuguese language capacity. It should be noted, however, that there is considerable goodwill on the part of all parties and multiple instances highlighting supportive, collaborative efforts have been noted in this report.

Second, technical guidance was a noted challenge around the HPV vaccine demonstration project which stymied efforts to ensure smooth, uninterrupted implementation. Providing technical guidance documents that are specific to the demonstration project would allow countries to better understand the objective of the demonstration project and how the implementation process should relate to eventual national introduction.

Third, it should be noted that the challenge around the implementation of the census also reflected underlying data quality issues. These data quality issues were present for other funding streams such as PCV and the difficulty in developing an M&E framework for HSS.

Positive and negative unintended consequences

A positive unintended consequence of Gavi support through the introduction of new vaccines is that weaknesses within the healthcare system have been exposed. For example, there were gaps in the cold-chain that had to be remedied in order to add new vaccines. Other health system weaknesses, such as limited human resources for health, specifically in management roles at the central level, are restricting the country's ability to effectively plan, execute and manage the expanding program. Finally the monitoring and evaluation system for immunization is ineffective, to the point where HMIS data is difficult to use for monitoring and other essential planning activities. Most of these challenges are subsequently targeted as part of the upcoming HSS grant.

An important unintended consequence of Gavi support is the sheer number Gavi support streams are presently unmanageable, most notably at the central level, where capacity is limited. As in many resource limited settings with multiple donors, there is sizeable internal "brain drain;" thus, turnover is common at the MOH and management of Gavi support is often the responsibility of recently appointed managers. There is need for a clearer and coordinated effort to plan multiple Gavi support streams for Mozambique. Although the IRC has noted the importance of prioritizing the HSS implementation, this

does not appear to be the case to date. Furthermore, with multiple introductions planned for 2015 and given the challenges presently faced, an explicit assessment of the capacity of Mozambique and partners to implement this large portfolio of work is clearly needed.

Related to the number of Gavi support streams was the specific unintended consequence we observed as a result of the increased priority given to the new Gavi support window for IPV. The limited timeframe for application and implementation of IPV coupled with the aforementioned central capacity constraints, we noted that the prioritization of IPV was a partial contributor to the slow progress in the implementation of the HSS support stream.

Chapter 4: Uganda

Uganda

Gavi support for Uganda

Uganda first received Gavi support in 2001 with the introduction of hepatitis B vaccine and immunization services support (ISS); since that time it has introduced *Haemophilus influenzae* (Hib) vaccine and pneumococcal conjugate vaccine (PCV) and utilized cash support for injection safety (INS) and Health system strengthening (HSS) windows, receiving a total of US\$190.6 million in Gavi funds to-date.

Table 24: Streams of Gavi support in Uganda

Gavi support	Period of support	Total amount of funding (US\$)
Pneumococcal conjugate vaccine (PCV)	2013-2015	47,929,326
Pentavalent vaccine	2002-2015	162,650,995
Health system strengthening (HSS)	Approved in 2008, disbursed in 2012-2014 (2013 funds reprogrammed to 2015)	19,242,000
Immunization services support (ISS)	2001-2004	9,230,520
Injection safety support (INS)	2002-2004	1,207,299
HPV vaccine (national introduction)	2015-2016	21,270,000
Inactivated polio vaccine (IPV)	2015-2017	8,779,500
Vaccine introduction grant (VIG)	2002, 2013, 2015	4,165,500

Source: <http://www.gavi.org/country/all-countries-commitments-and-disbursements>; accessed last April 21, 2015
Values shown represent Gavi commitments, those which Gavi intends to fund over the life span of the program, subject to performance and availability of funds.

Methods overview

Consistent with the prospective nature of the FCE, the evaluation has paralleled all Gavi-supported activities, assessing implementation and related milestones by support stream. The table below provides an overview of methods used, sources of data, and topics assessed.

In Uganda during 2014, an analysis of the immunization partnership was conducted in order to understand how national-level partners worked together during the HPV vaccine application process and assess the consequences of partnership structure, practices, and performance on the process (Annex 11). Seven KIIs were conducted, focusing specifically on partnership. Network surveys were completed during these interviews and four additional key informants were interviewed to document working relationships and trust among partners. Partnership methods, analyses and graphs are described in greater detail in Annex 11. These approaches and tools will be implemented in other countries in 2015, with the goal of integrating them into routine, ongoing process-tracking activities.

Table 25: Evaluation methods

Methods	Source consulted	Topics investigated
Process tracking	<ul style="list-style-type: none"> - Collected and reviewed documents including Gavi applications and guidelines, Gavi decision letters, operational plans and budgets, meeting minutes, and various reports including the HPV vaccine demonstration report, WHO PCV10 readiness assessment report, MOH HSS status update report, IRC reports, joint appraisal report, and APRs. - Conducted brief interviews to confirm factual information. - Observed EPI technical meetings, NCC meetings, Gavi coordination committee meeting, PCV health worker trainings and mentorship in select districts, and meetings between Gavi and country stakeholders (including the APR and joint review). 	<ul style="list-style-type: none"> - Information was collected based on relevant TOC milestones for PCV, HSS, ISS, HPV, and IPV.
Key informant interviews (KII)	<ul style="list-style-type: none"> - Conducted 24 country-level KIIs at the national and subnational levels (including KIIs in Bududa, Busia, Gulu, Ibanda, Isingiro, Kayunga, Lira, Oyam, Sheema, and Tororo districts) with government, WHO, and other partner organizations. - Conducted 9 KIIs with global-level staff from the Gavi Secretariat and Alliance partners. 	<ul style="list-style-type: none"> - Information was collected based on relevant TOC milestones for PCV, HSS, ISS, HPV, and IPV.
Stakeholder network analysis survey	<ul style="list-style-type: none"> - Conducted 11 stakeholder network analysis surveys on partnership with country-level key informants. 	<ul style="list-style-type: none"> - Examined working relationships and trust among partners.
Analysis of administrative data on vaccine coverage	<ul style="list-style-type: none"> - Analyzed UNEPI/WHO vaccine coverage data. 	<ul style="list-style-type: none"> - Scale-up and routinization of PCV
Small area analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey and census data sources. 	<ul style="list-style-type: none"> - Estimated district-level vaccine coverage and child mortality.
Inequality analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey data sources of 	<ul style="list-style-type: none"> - Estimated vaccine coverage differences by wealth quintile and gender.

household wealth and
vaccination coverage,

Findings

The Full Country Evaluations have compiled and systematically analyzed relevant data on key indicators at the national and, when possible, subnational levels (Table 27, Table 27).

Table 26: Country characteristics of Uganda

Characteristic	
Demographic and economic indicators	
Total population (2013)	37.58 million
Birth cohort (2013)	1.66 million
GDP per capita (2014)*	US\$572
Health spending and Development Assistance for Health **	
Government health expenditure as source	US\$266 million
Development Assistance for Health, channeled through government	US\$119 million
Development Assistance for Health, channeled through non-government entities	US\$334 million
Total Development Assistance for Health	US\$453 million

*GDP per capita source: IHME covariates database, reported in 2005 international dollars

** Health expenditure is explained in terms of government health expenditure as source (GHE-S), DAH channeled through government (DAH-G), and DAH channeled through non-government entities (DAH-NG). GHE-S + DAH-G gives the total government health expenditure, GHE-S + Total DAH gives total spending on health in the country. Health expenditure estimates 2011; Gavi disbursements 2001–2012.

Table 27: Vaccine coverage estimates in Uganda

Vaccine coverage	Most recent survey estimate*	WUENIC 2013 revision**	Self-reported coverage (WHO)***
DPT/Penta3 coverage	71.5%	78%	78%
DPT1–DPT3 dropout rate	21.6%	11%	11%
BCG coverage	93.7%	93%	82%
Polio3 coverage	62.9%	82%	82%
Measles coverage	75.8%	82%	82%
Percent fully vaccinated****	51.6%	N/A	N/A

* Most recent survey coverage estimates from 2011 DHS

** WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) 2013¹³

***WHO vaccine-preventable diseases monitoring system, 2014 global summary¹⁴

**** BCG, measles, and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth).

Table 28: Child, adult, and vaccine-preventable disease mortality in Uganda

Child, adult, and vaccine-preventable disease mortality	GBD2013*
All-cause mortality (risk per 1,000)	
Infant mortality ($_{1q_0}$)	52.9 (44.5, 60.5)
Under-5 mortality ($_{5q_0}$)	80.1 (69.4, 93.1)
Female adult mortality ($_{45q_{15}}$)	295.4 (276.0, 318.7)
Male adult mortality ($_{45q_{15}}$)	362.8 (333.3, 396.5)
Cause-specific mortality: children under 5 (rate per 100,000)	
Measles	26.1 (4.6, 80.7)
Diphtheria	0.15 (0.00-0.94)
Tetanus	6.1 (2.9-9.9)
Pertussis	13.7 (0.0-61.3)
Meningococcal infection	7.0 (3.6-11.4)
Diarrheal disease	122.2 (60.9-175.0)
Lower respiratory infections	213.6 (146.4-301.5)
Cause-specific mortality: all ages (rate per 100,000)	
Cervix uteri cancer	6.1 (4.2-8.1)
Acute hepatitis B	0.7 (0.5-0.9)
Cirrhosis of the liver secondary to hepatitis B	2.8 (1.7-4.0)
Liver cancer secondary to hepatitis B	1.0 (0.5-1.5)

* Mortality based on GBD 2013 estimates

Resource tracking

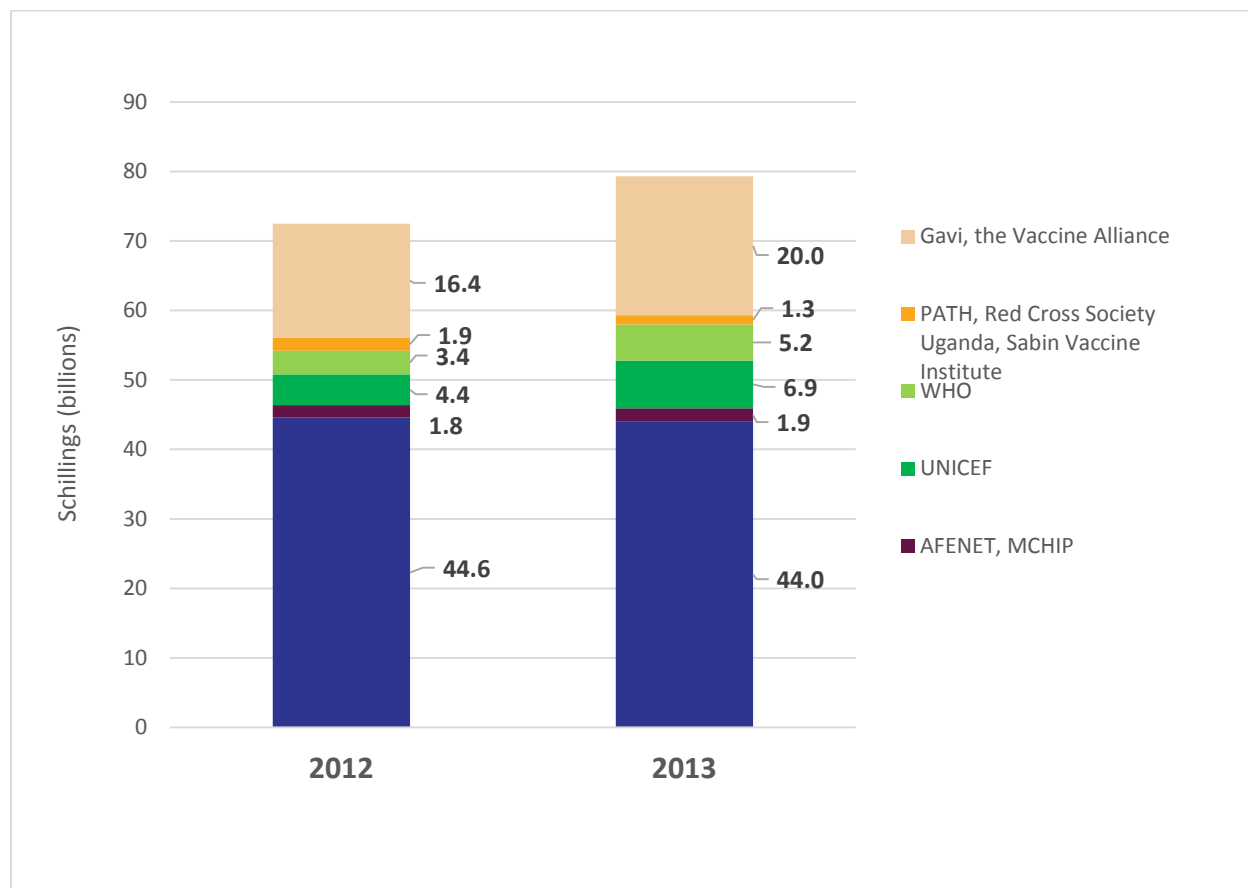
The FCE team conducted a detailed immunization resource tracking study in Uganda, led by HealthNet Consult (Annex 10).²⁹ Due to the timing of the Ugandan fiscal year, this report contains results from the 2013 RT exercise, which analyzed 2011/2012 and 2012/2013 resources for immunization. The 2013 resource tracking study leverages work undertaken by HealthNet and partners as part of the EPIC study (Brenzel L, Young D, Walker DG [forthcoming]) and is an adaptation of the 2011 system of health accounts (SHA) methodology to estimate the total envelope of resources for immunization activities in 2012. For detailed methods and results, see Annex 10.

The primary funding sources for immunization in Uganda are the government of Uganda and Gavi.

Funding sources were assessed in two ways:

- Scenario 1: If personnel costs are included, the total amount of funds to support immunization activities in 2013 was 79.3 billion shillings, with government contributions representing 55% of all spending on immunization and Gavi representing 25% (Figure 41).
- Scenario 2: If personnel costs are excluded, the total amount of funds supporting immunization activities in 2013 was 49.4 billion shillings, with government spending reducing to 29% (Figure 42).

Figure 41: Total sources of financing for immunization in Uganda in 2012 and 2013 in billions of UGX, Scenario 1⁴⁵

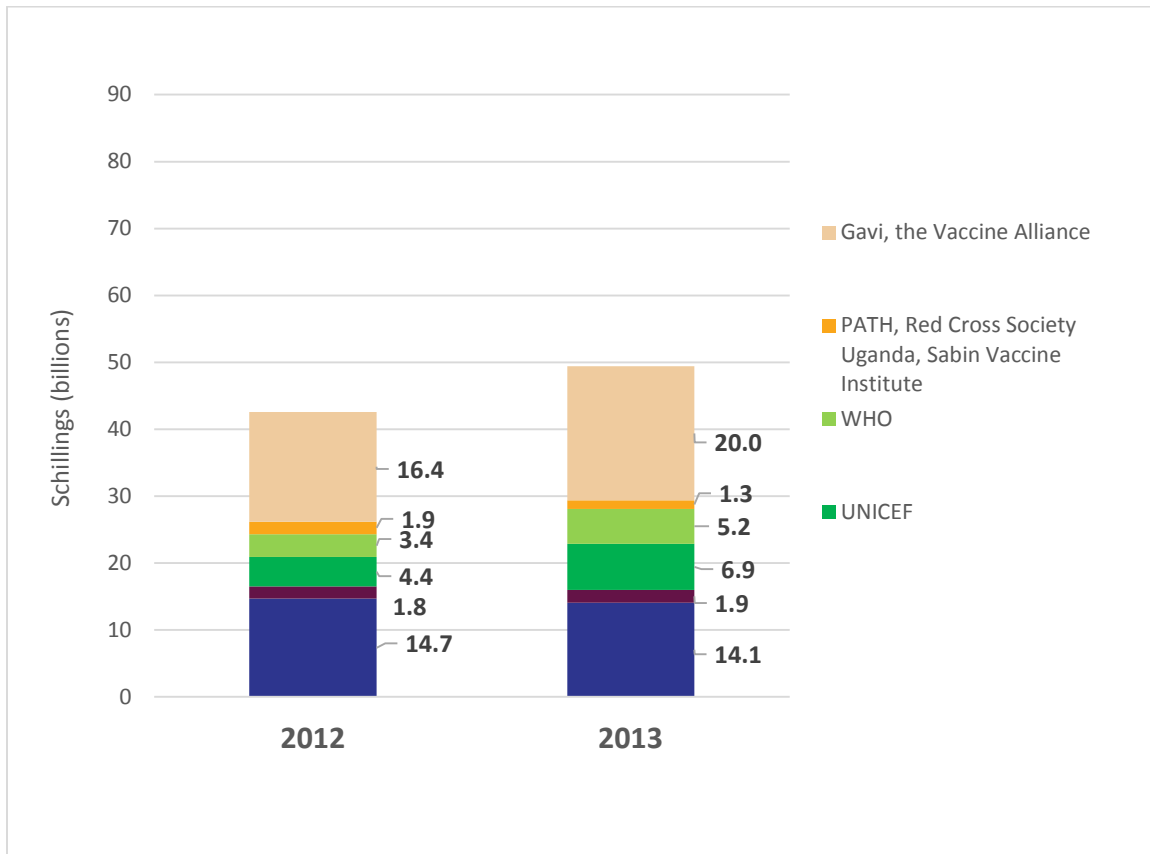


⁴ Abewe, C., et al. (2014). *Uganda resource tracking (2011/12 - 2012/13)*. Makerere, Uganda: HealthNet Consult, Makerere School of Public Health, Infectious Diseases Research Collaboration.

This report can be accessed in Annex 10.

⁵ The methodology used in the resource tracking work was a Systems of Health Accounts (SHA). SHA has a specific financial mapping coding system. The coding system tends to group organizations together based on their sources of funding or type of organization. For example FS.2 code in the annex groups transfers distributed by government from a foreign origin. AFENET and MCHIP fall under F.S 2.1.1.1 which is USG bilateral financial transfer, PATH,RED Cross, and SABIN fall under FS 2.4.3. which is external/NGO source financial transfers.

Figure 42: Total sources of financing for immunization in Uganda in 2012 and 2013 in billions of UGX, Scenario 2



The majority of resources are spent on facility-based routine immunization service delivery, which in this study includes expenditure on immunization outreach due to difficulty in teasing out expenditures specific for outreach-based services. The second largest category, which also grew in proportion from 2012 to 2013, was special programs (new vaccine introduction, campaigns, cars to support regional referral hospitals and computers for EPI at national level), which represented 4.4 billion UGX and 12.4 billion UGX of the total funding in 2012 and 2013, respectively (Figure 43).

Figure 43: Sources of immunization expenditure in 2012 and 2013 in billions of UGX, Scenario 1

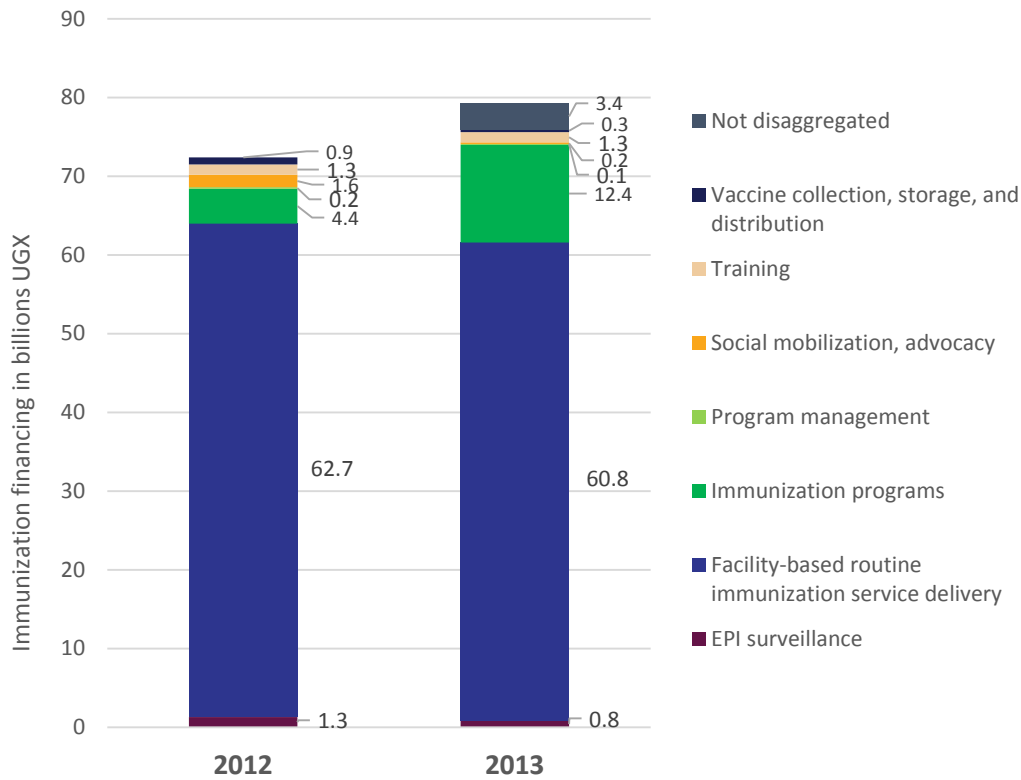
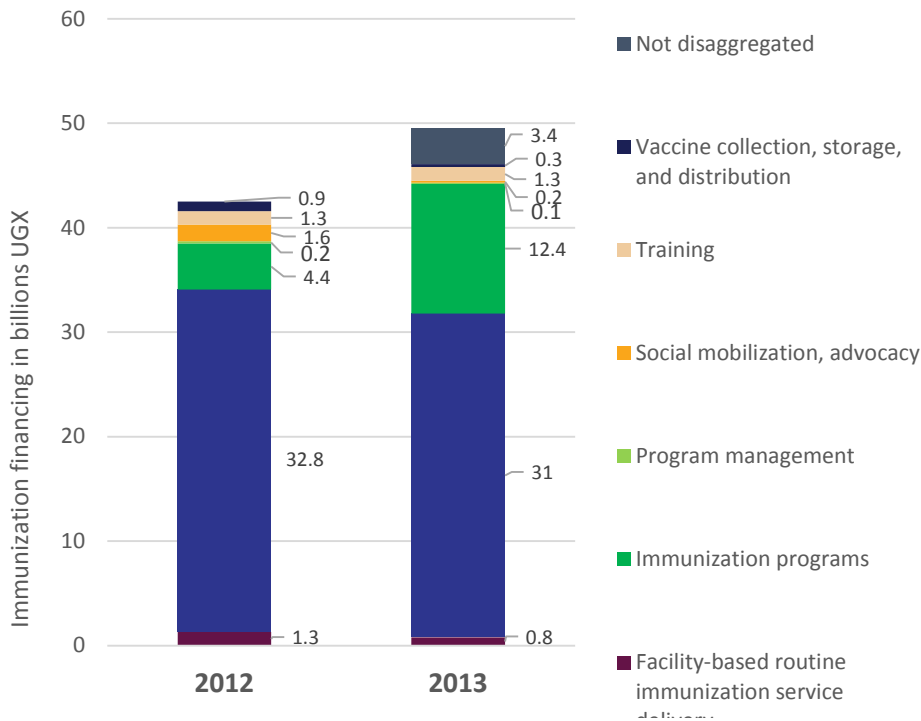
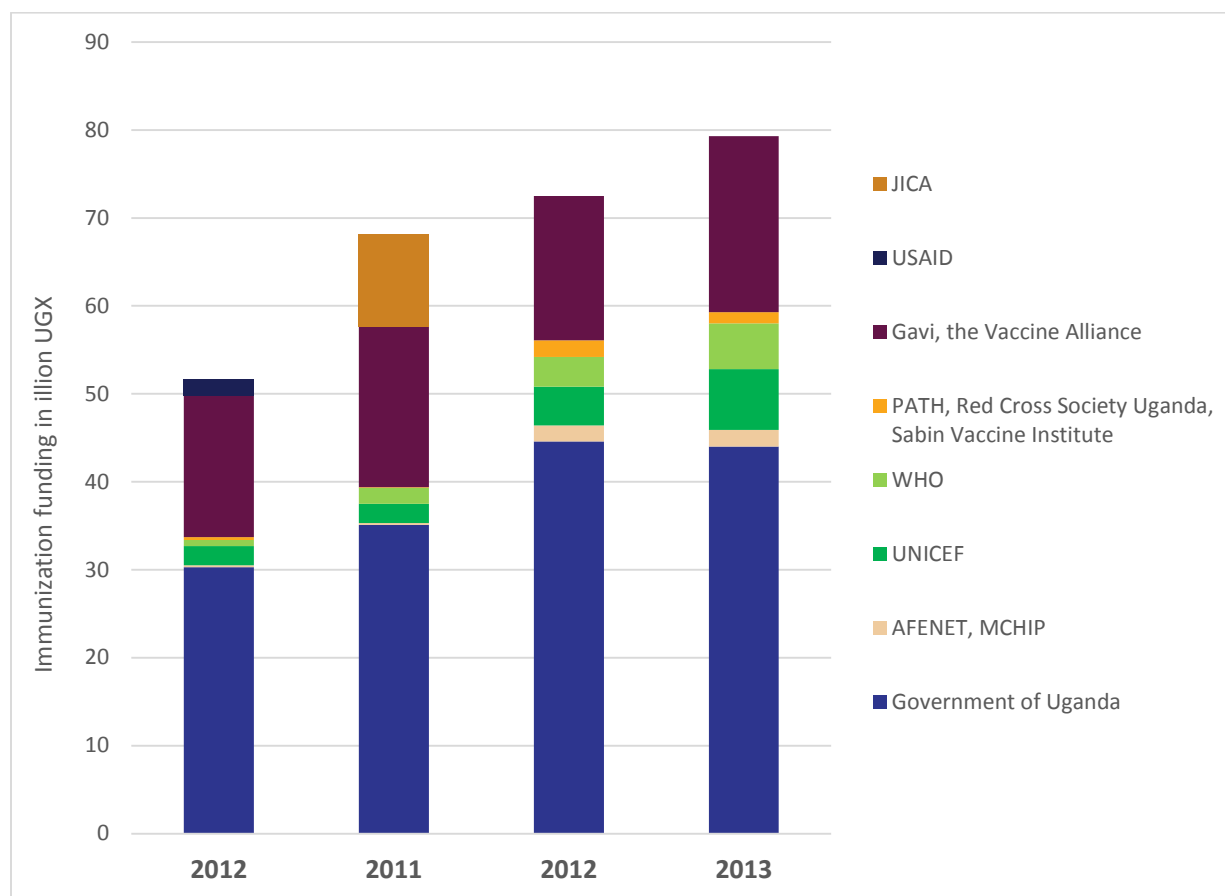


Figure 44: Sources of immunization expenditure in 2012 and 2013 in billions of UGX, Scenario 2



When we incorporate the results from the previous EPIC study, the growth in the resource envelope for immunization is notable (Figure 45). The GOU contribution is substantial. GOU contributions have decreased as a percentage of total funding and since 2012 have plateaued in total amount. From a financial sustainability perspective, it is encouraging that GOU resources for immunization have grown in line with an overall increase in the resource envelope. External support still accounts for more than 40% of the envelope, with Gavi remaining the most significant contributor. Gavi contributions are likely to increase, as most of the Gavi-supported PCV rollout was concentrated in 2014 and new Gavi support, like HPV vaccine, is upcoming. Another positive sign for financial sustainability is the increasingly diverse body of contributors, which now include USAID, African Field Epidemiology Network (AFENET), USAID's Maternal and Child Health Integrated Program (MCHIP), UNICEF, WHO, PATH, Red Cross Society Uganda, and Sabin Vaccine Institute.

Figure 45: Trends in sources of funding for immunization in Uganda from 2010 to 2013 in billions of UGX, Scenario 1⁶



⁶ Abewe, C., et al. (2014). *Uganda resource tracking (2011/12 - 2012/13)*. Makerere, Uganda: HealthNet Consult, Makerere School of Public Health, Infectious Diseases Research Collaboration.

This report can be accessed in Annex 10.

Analysis of immunization coverage, child mortality, and inequality

The FCE systematically compiled and analyzed all available data sources to estimate immunization coverage and child mortality by geography, household wealth, and gender. These estimates should be interpreted with caution: in some cases different surveys give disparate results, suggesting issues with data quality, and not all data are identified at the lowest geographic level. National-level estimates of vaccine coverage in Uganda (*Table 27*) conceal highly variable coverage rates among districts, as shown in *Figure 46* and *Figure 47*). In 2013, approximately one in five districts had achieved DPT coverage rates in excess of 90%; at the same time, in several districts coverage was less than 65%. Full vaccination coverage was even more variable, with coverage exceeding 80% in some districts while still below 40% in several others. Interestingly, districts with relatively low full vaccination coverage can be found spread throughout the country, though there are localized clusters. District-level maps of coverage in 2000 and 2013 are available for all antigens (BCG, measles, three doses of DPT, three doses of pentavalent, and three doses of polio) in Annex 3.

As part of the FCE, we systematically compiled and analyzed all available data sources to estimate immunization coverage and child mortality by geography, household wealth, and gender. We find an increase in median coverage among districts for all antigens. At the same time, progress in reducing inequalities between 2000 and 2013 was more mixed; there are notable declines in between-district inequality in both BCG and measles vaccination coverage, and notable increases in between-district inequality in polio and full vaccination coverage, as measured by the range and interquartile range.

Figure 46: District-level DPT3 coverage in Uganda, 2000 and 2013

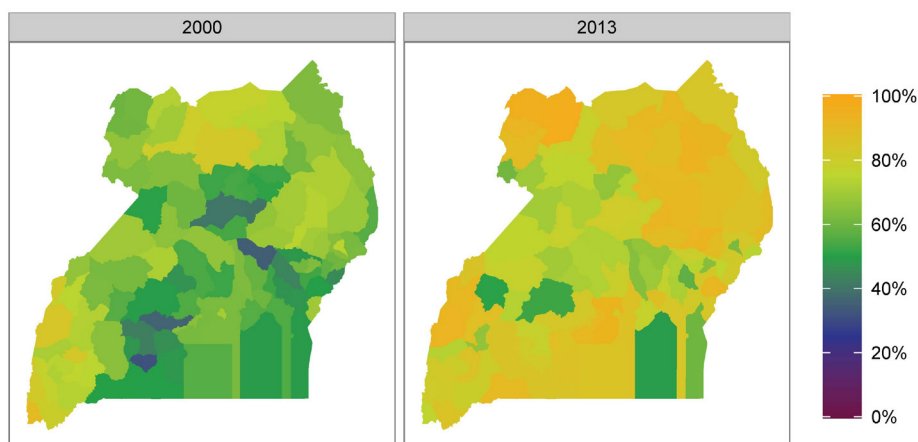
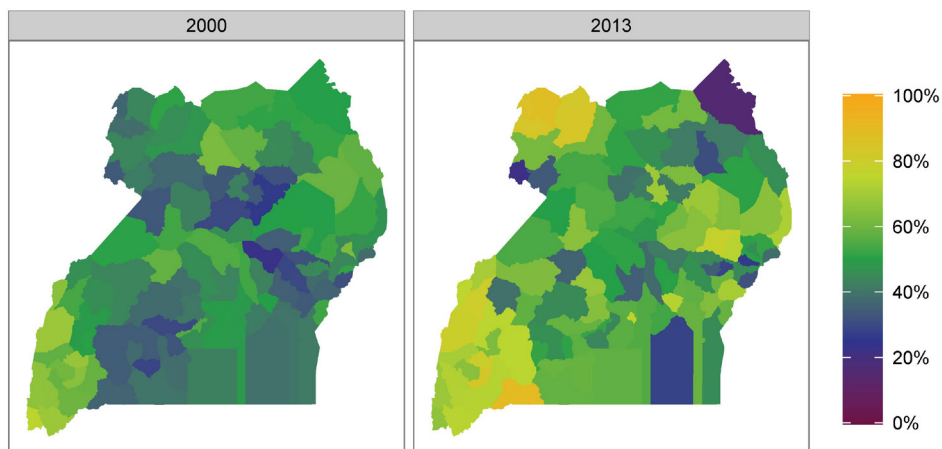


Figure 47: District-level fully-vaccinated child coverage, Uganda, 2000 and 2013

In addition to within-country place-based inequalities, we find evidence of inequalities in vaccine coverage by household wealth (Figure 49). In the two years in the 1990s where we are able to observe the ratio of DPT vaccine coverage in the richest income quintile to coverage in the poorest income quintile, this ratio is considerably above one. In the two years in the 2000s where we again observe this ratio, it is much closer to one, though in the most recent year there is still evidence that it exceeds one. In both decades there is little evidence of inequality in vaccine coverage between male and female children: the ratio of coverage among male children to coverage among female children is indistinguishable from one in all periods.

Figure 48: Distribution of district-level vaccination coverage and under-5 mortality in Uganda, 2000 and 2013

The horizontal line represents the median across districts. The thick vertical bar represents the interquartile range, while the thin vertical bar represents the range across districts

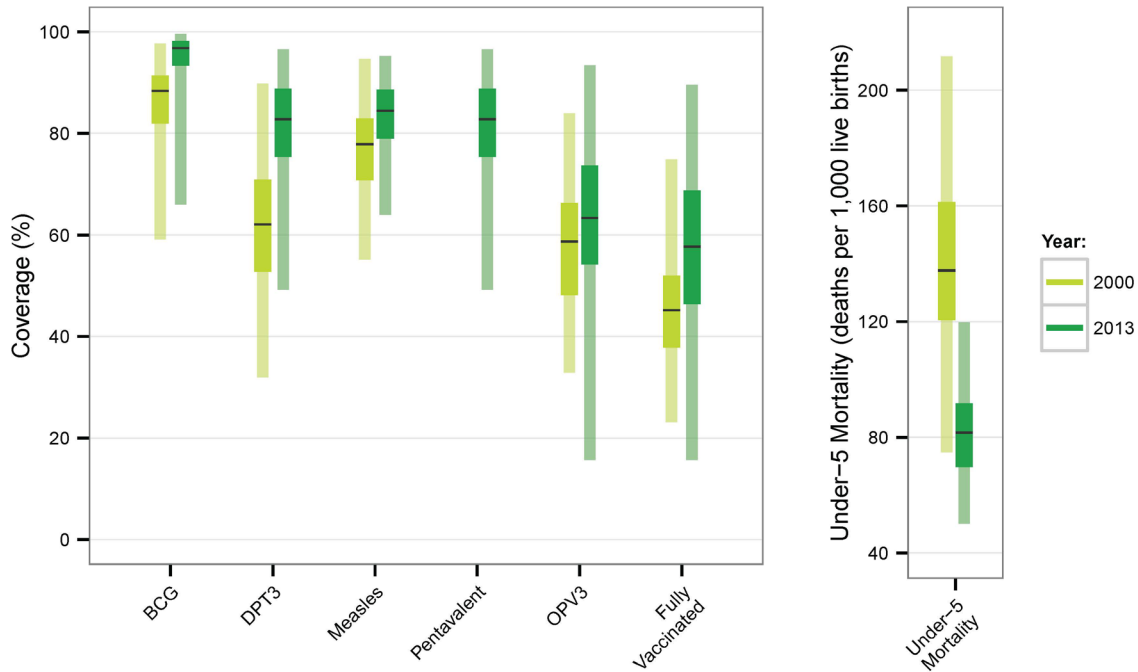
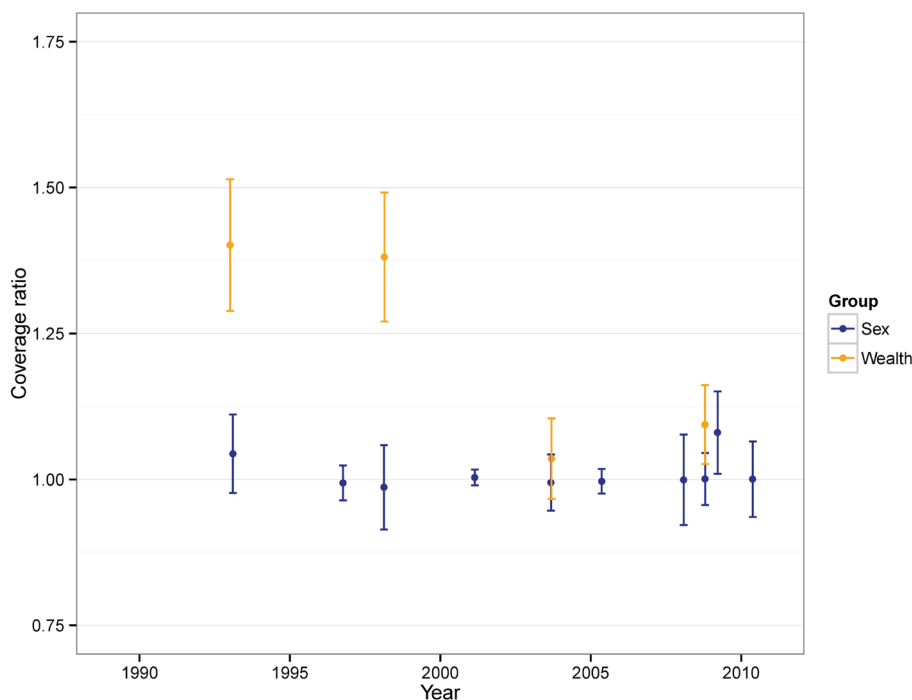


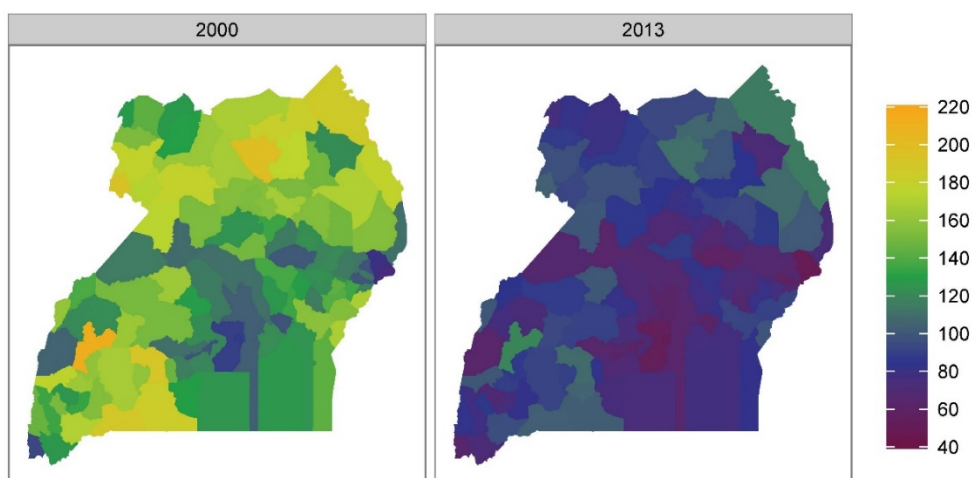
Figure 49: Inequality ratios of DPT3 vaccine coverage

Wealth ratio is the ratio of DPT3 coverage in the richest quintile to coverage in the poorest quintile. Sex ratio is the ratio of DPT3 coverage in males versus females.



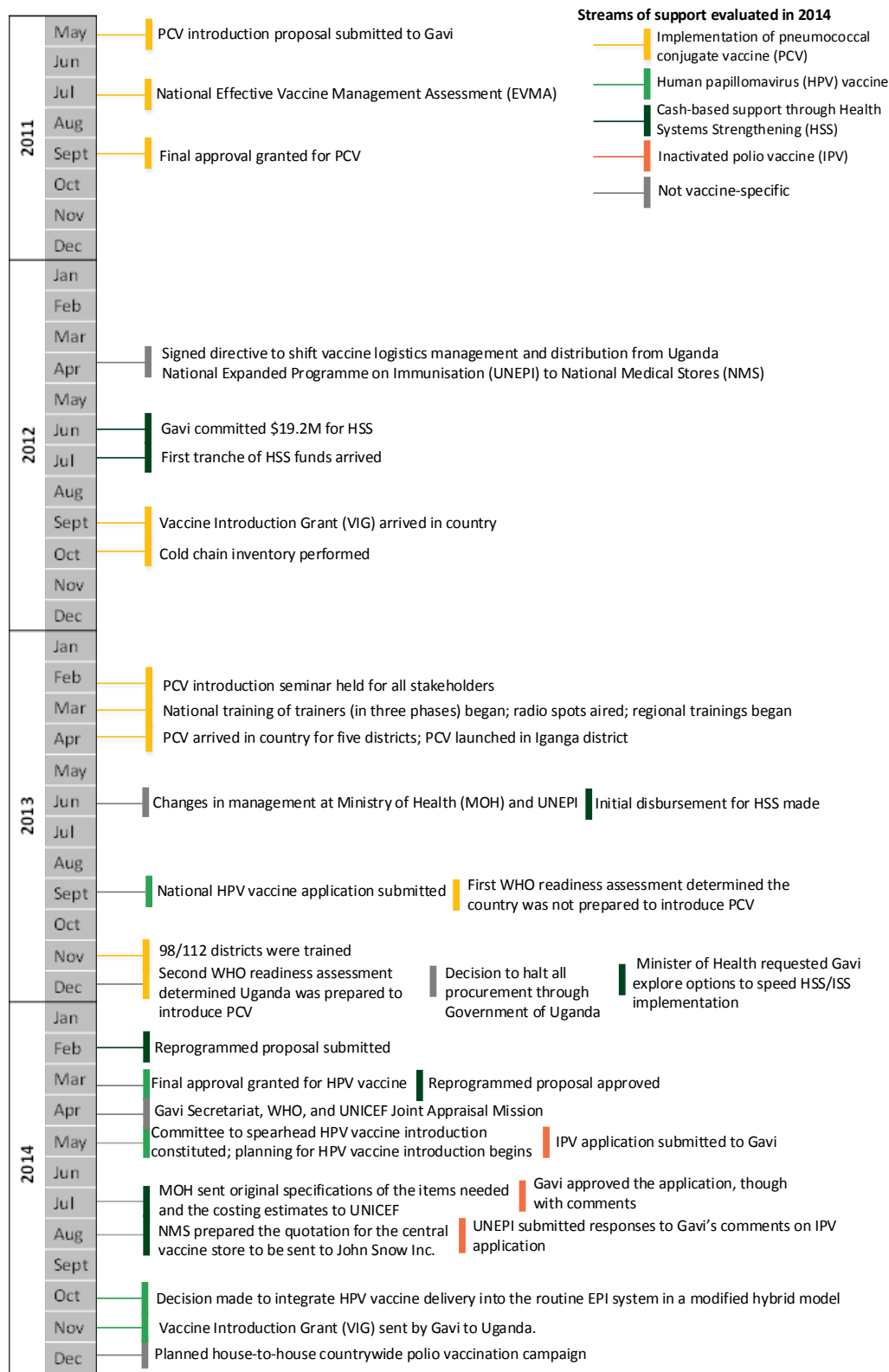
National-level estimates of under-5 mortality (*Table 28*) similarly mask large disparities in under-5 mortality among districts, as illustrated in Figure 49 and Figure 50. In both 1990 and in 2013, children living in districts in the north and southwest generally experienced greater risk of under-5 mortality than children living in districts in the southeast. Mortality declined in all districts over this period, and at the same time the between-district inequality in under-5 mortality, as measured by the range and interquartile range, has also declined. Nonetheless, considerable disparities remain in 2013, with district-level under-5 mortality risks exceeding 100 deaths per 1,000 live births in approximately 12% of districts.

Figure 50: District-level under-5 mortality, Uganda, 2000 and 2013 (deaths per 1,000 live births)



Overview of major immunization events

Figure 51: Timeline of major immunization events in Uganda



Human papillomavirus vaccine

Summary of progress

In September 2013, the government of Uganda applied for Gavi support to introduce HPV vaccine nationally; this was approved in March 2014. The vaccine is scheduled for introduction in April 2015. Table 29 summarizes the progress and successes as well as the challenges and responses associated with the preparations to introduce HPV vaccine nationwide.

The successful application for Gavi support to introduce the HPV vaccine nationally was preceded by a demonstration project of HPV vaccine delivery in selected districts in Uganda. The demonstration project was implemented by the MOH and Ministry of Education (MOE) with assistance from PATH and Reproductive Health Uganda. It was financed through a grant from the Bill & Melinda Gates Foundation and provided evidence that enabled Uganda to satisfy the Gavi requirement that countries demonstrate the ability to deliver HPV vaccine to adolescent girls.⁷

The demonstration project was launched in 2008 and aimed to assess the feasibility, acceptability, and cost of delivering HPV vaccine. It initially began in two districts, Nakasongola and Ibanda, each testing a different delivery approach. In Nakasongola district, delivery of HPV vaccine was tested through the biannual Child Days Plus (CDP) approach and the target population was girls 10 years of age. The CDP approach integrates HPV vaccine into existing health campaigns of preventive and treatment interventions, including vitamin A supplementation, deworming, catch-up immunization, and treatment of neglected diseases. In Ibanda district, a school-based approach was used and the target population was based on school grade (Primary 5), or 10 years of age for girls who were not attending school. These approaches are summarized in Table 30.

The demonstration report indicated that the HPV vaccine was highly acceptable in communities and that implementation was feasible. A coverage survey in 2009 showed 88.9% coverage with the school-based delivery strategy and 60.7% coverage with the CDP delivery strategy.²⁹ Based on the success in the two districts, the demonstration project shifted to using a combined approach of integrating the CDP with school-based immunization, and HPV vaccine immunization was extended to 12 additional districts in 2012. The new combined approach targeted all girls in Primary 4, regardless of age, and 10-year-old girls who were not in school. Vaccination of the first cohort of girls in the 12 new districts began in September 2012; the second dose was administered in November 2012 and the third dose between March and August 2013.

The application to Gavi for national adoption of HPV vaccine was prepared between May and September 2013. The application process was reported to have been smooth and effective. Based on the partnership analysis conducted (Annex 11), respondents attributed the effective partnership to previous experience with PCV introduction and polio campaigns and the HPV vaccine demonstration project, to the existence of trust between partners, and to the political priority around HPV. A KII at a country-level partner institution stated:

⁷ Demonstrated ability is defined as prior experience in delivering multi-dose vaccines to at least 50% of a target population of 9- to 13-year-old girls in an average-sized district. <http://www.gavi.org/support/nvs/human-papillomavirus-vaccine-support/#sthash.wK4V6Xld.dpufrequirement> demonstration project.

The main reason for the high partner involvement was due to the importance of cervical cancer to the country. It is the leading cause [of] death to women compared to other cancers. (KII, partner organization)

The new team of managers at UNEPI was also identified to have a positive influence on the functioning of the partnership and on the timely submission of the HPV vaccine application.

Originally, WHO and UNICEF were the major players but in recent years many more partners have come on board. The new EPI management has rejuvenated the partnership and all the partners come together under the EPI technical committee. (KII, partner organization)

Finally, PATH, who became a key immunization partner during the demonstration project, was identified as a “champion” for HPV that worked behind the scenes to move the process along:

PATH played a critical role. PATH continued reminding MOH of the need to prioritize the HPV [vaccine] introduction. (KII, partner organization)

The partnership for the application process was mainly driven by UNEPI (program manager and other colleagues) and PATH. (KII, partner organization)

In contrast, the Ministry of Education did not attend application meetings.

What I didn't see was Ministry of Education at application. They participated in demonstration but not application. We could have actually involved them much more but we just didn't. (KII, MOH)

The absence of the MOE was an issue also raised by the IRC in the initial review of the application. Unless prompted, respondents did not mention the Gavi Senior Country Manager (SCM) during partnership interviews, which is consistent with the way the SCM described their role – to provide comments on the application, but not technical assistance during application development. More concerning, key informants did not identify participants from the Ministry of Finance, an observation which is consistent with other network-based^{30, 31} and policy studies^{32,33} of new vaccine decision-making. The Education and Finance Ministries are required to sign the HPV vaccine application and did so, but did not participate actively in the drafting of the application. We explore the consequences of those stakeholders' absences on financial sustainability and delivery strategies in the analysis section.

Respondents reported high levels of trust during the application process, particularly for other individuals with whom they had a history of working, but also noted that the process of working in a partnership may have drawn out the time it took to prepare the application. Nevertheless, the process resulted in buy-in and ownership around the introduction of HPV vaccine within the Ministry of Health, which was in contrast to the rushed process and lack of ownership in the subsequent IPV application process.

Yes, the HPV application partnership facilitated country ownership of the process unlike IPV application process. (KII, MOH)

The results of the partnership analysis are summarized below, with full methods and results described in Annex 11.

Figure 52: Partnership framework results for HPV vaccine application process

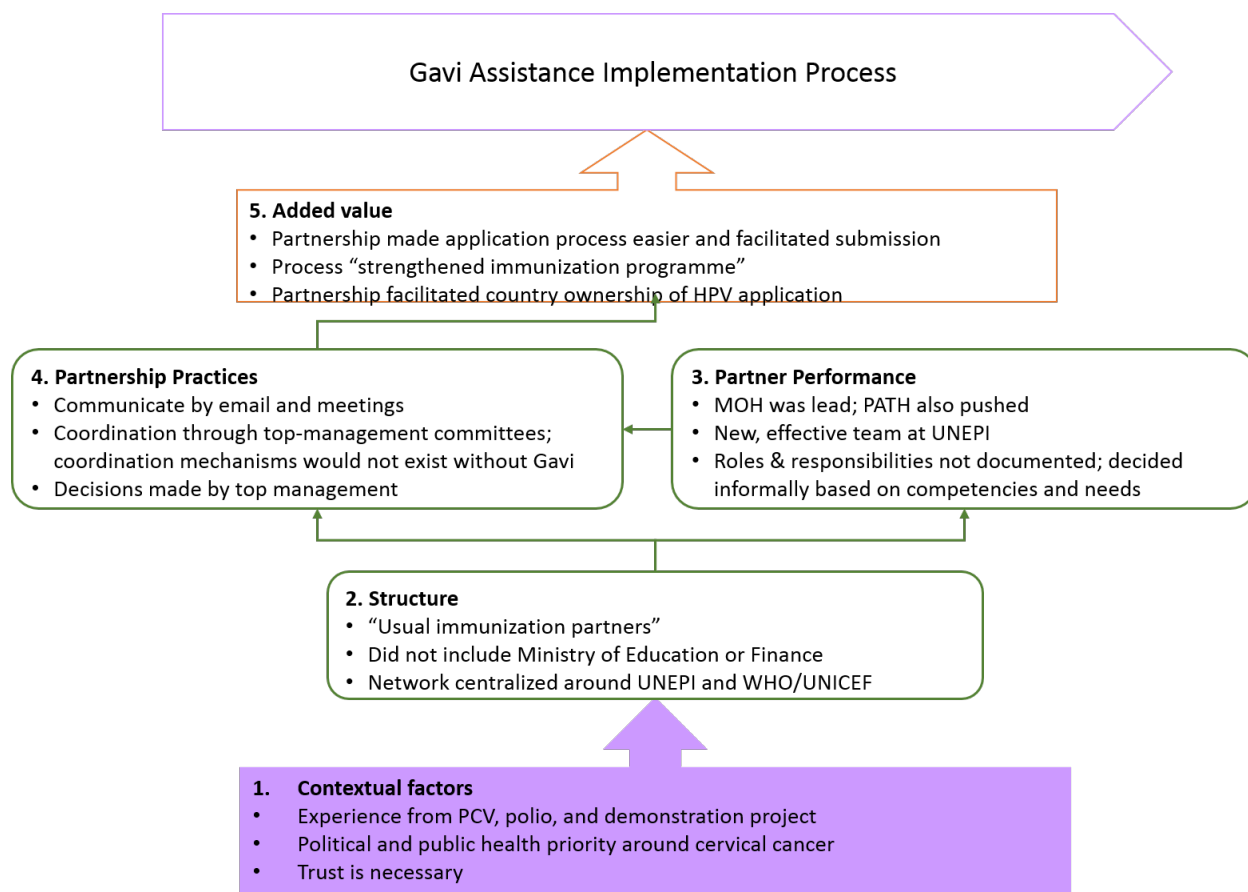


Table 29: Summary of country progress

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Timely and adequate planning and budgeting for HPV vaccine national introduction	
<ul style="list-style-type: none"> Planning for implementation started in May 2014 while rollout is expected in April 2015. A comprehensive HPV vaccine introduction plan and budget was submitted to Gavi in September 2013 with the application. Final approval granted in March 2014. A committee to spearhead the HPV vaccine introduction process was constituted in May 2014. 	<ul style="list-style-type: none"> Country planned to implement a three-dose schedule, but switched to a two-dose schedule following revised recommendations from WHO and Gavi. Following switch from three-dose to two-dose schedules, UNEPI must re-quantify the number of doses applied for and revise co-financing structures.

<ul style="list-style-type: none"> - Subcommittees to oversee different aspects of the introduction process were constituted by the EPI technical meeting on August 20, 2014: <ul style="list-style-type: none"> o Coordination and planning subcommittee (chaired by EPI Manager) o Social mobilization subcommittee o Ministry of Education subcommittee o Surveillance subcommittee o Training subcommittee o Resource mobilization subcommittee 	<ul style="list-style-type: none"> - Two months of planning time have been devoted to determining the service delivery model to be used.
Appropriate technical assistance provided	
<ul style="list-style-type: none"> - PATH and Reproductive Health Uganda provided technical assistance for the HPV vaccine demonstration project to the MOH and Ministry of Education, the implementing agencies. The diverse set of stakeholders worked effectively as a partnership (see partnership study in Annex 11). - PATH remained in the partnership and continued to provide technical support during the HPV vaccine application process, drawing on lessons learned from the demonstration. 	
Sufficient funding available in time	
<ul style="list-style-type: none"> - Gavi approval was secured far in advance of scheduled introduction (approval secured in March 2014, introduction expected in April, 2015) - The HPV VIG for national roll-out was disbursed from Gavi to the country on November 20, 2014. - The HPV subcommittee meeting (June 26, 2014) resolved that the Director General will write to Gavi requesting for release of VIG funds. 	<ul style="list-style-type: none"> - The process of initiating release of approved funds from Gavi is not clear.
Cold-chain and logistic system prepared for HPV vaccine	
<ul style="list-style-type: none"> - Expansion of cold-chain space will largely rely on purchase of refrigerators under the HSS grant. UNICEF was expected to supply fridges by December 2014; now this has been delayed to March 2015 according to an MOH timeline. - Cold-chain assessment concluded in September 2014 (the final report has not yet been released). 	<ul style="list-style-type: none"> - Procurement of cold-chain equipment and construction of the central vaccine store is delayed due to delayed implementation of the HSS grant.

Analysis of major challenges and successes

As part of the Gavi FCE, we identified two findings as part of the government of Uganda's preparations to date to introduce HPV vaccine, which are discussed further in this section.

Finding 1

Key steps in the application process failed to account for the feasibility, sustainability, and ongoing financial resources required for the chosen and tested HPV vaccine delivery model (a combination of school-based and campaign-based delivery) for national introduction. These failures include lack of participation in the application development process on the part of key partners who could have provided this financial perspective, and failure of the Independent Review Committee (IRC) review process to ensure that this information was provided prior to approval of the application. This led to a switch to a delivery model based on routine EPI that was not one of the primary models tested as part of the HPV vaccine demonstration project in Uganda.

In the approved proposal for introducing HPV vaccine nationwide in Uganda, a hybrid approach combining the CDP and school-based approach was identified as the delivery model. After the application and approval process, there has been debate among the MOH and country partners about whether the hybrid approach is appropriate based on feasibility and sustainability considerations. The debate on the sustainability of the proposed delivery model for HPV vaccine was triggered by reports that some of the 14 demonstration site districts were unable to continue to deliver HPV vaccine following the end of support from partners. Some districts completely stopped delivering HPV vaccine after partner support ended, whereas others continued but with suboptimal delivery of the vaccine and unintended consequences for routine immunization. Ibanda district, for example, still continued to deliver HPV vaccine through CDP and primary health care (PHC) funds, but consequently had to reduce the number of routine outreach visits, which has led to a drop in coverage for routine vaccines. Reports by MOH supportive supervision teams also indicated that HPV vaccines had expired in some districts after not being delivered as planned.

When we started implementing HPV in September 2012, we received funding for outreaches in schools. All of a sudden the funding stopped in 2013. There was no money to facilitate outreaches for the third dose. Now health workers aren't willing to go to schools for HPV vaccination. (KII, implementing district)

The country is not likely to sustain mass HPV immunization campaigns and health workers going to schools for HPV vaccination as these would require a separate budget. (KII, MOH)

When the HPV vaccine demonstration project ended not only did partner funding end, but this was compounded by reduced CDP funds for districts. This indicated that it was likely there would be limited CDP funds to support continued HPV vaccine delivery. However, the plan for national scale-up was to use the hybrid model to deliver HPV vaccine through CDP funds for doses 1 and 3, and through district-level primary health care (PHC) funds for the second dose (that did not coincide with CDP).

We planned on delivering the vaccine using Child Days Plus... but when we did that even in the back of our heads we knew that there were some slight funding challenges, but we thought maybe...those would be sorted out... In the first years you would have Gavi support to deliver in

schools, perhaps this support would not be available in the subsequent years. That's where we think that they would be tapping onto the Child Days Plus and the PHC funding to actually deliver the vaccine. (KII, partner organization)

Our evaluation findings indicate that consideration and planning for long-term sustainability did not sufficiently take into account the instability of CDP funds or identify a viable alternative. The necessary resources and long-term sustainability of the specified delivery approach were not fully taken into account as part of the application and approval process for Gavi support for national introduction. This is indicated despite several prompts and information sources available at the time to inform a discussion and consideration of the long-term operational costs of the vaccine delivery strategies being proposed. First, the guidelines for national introduction of HPV vaccine specifically state that countries must “provide a report on the costing analysis of the proposed delivery strategy or strategies and evidence of non-Gavi resources to support delivery.”³⁴ Secondly, there were signs emerging from the demonstration districts in March-August 2013 that the sites were facing challenges regarding the sustainability of the delivery model. Third, there was a detailed costing analysis of the two delivery strategies used in the demonstration project that was conducted and published prior to the application, but this information was not included in the application to inform the ongoing cost of delivery.³⁵

It appears that none of the above triggers resulted in a thorough consideration of ongoing operational costs as the application was developed and the vaccine delivery strategy for national introduction was determined. The cost of the delivery model for HPV vaccine was not discussed in any of the three relevant HPAC meetings, according to the meeting minutes. None of the local researchers who participated in the costing study were identified as having participated in the application process through the partnership interviews. We also did not see mention of the costing analysis in the application materials that were submitted to Gavi. It is not clear why the guidelines of the application did not prompt these discussions during the committee meetings, or the inclusion of the required cost information in the application. We do note a couple of factors that may have contributed: in addition to the absence of the local costing study authors, our partnership analysis indicated that individuals from the Ministry of Finance did not participate in the application development; perhaps their involvement would have resulted in closer attention paid to budgeting and financing of these ongoing operational costs. We also note that although the guidelines include the requirement to include a cost analysis of the delivery strategies, the application form does not provide a question or field that prompts this specific cost information to be included.

One reason that the experience from the demonstration sites was not more fully considered was that the evidence was not widely known by the MOH and country-level partners at the national level until an assessment was conducted and results shared in an October 2013 report, which came out after the application was submitted.

Two districts were involved in the [original] demonstration. When the demonstration ended we got additional doses for vaccines for three years. We had to build sustainability plans right away so in the first year we supported [delivery] with 50% of funding, in the second year 0%. One district continued vaccinations, the other district failed to deliver vaccines.... At the time that the [HPV vaccine] application was submitted, we hadn't gotten full data about the discontinuation. (KII, partner organization)

The IRC review of the application does note the absence of a detailed budget, and they comment on their inability to assess the quality and sustainability of the proposal without this information. The

government of Uganda was required to respond to this request for clarification, and they did, submitting a detailed budget for the VIG. No information regarding the ongoing operational costs of vaccine delivery was provided in the response that would address the IRC's concerns about sustainability. The application was approved by Gavi, despite this lack of clarification about the sustainability and ongoing operational costs of vaccine delivery beyond the national introduction.

After the application was approved and the MOH and country-level partners began the planning process for introduction, the delivery strategies were revisited. An HPV coordination meeting was convened (June 26, 2014) to review various strategies based on the demonstration project in Uganda, as well as Rwanda, South Africa, and Vietnam, and recommended the hybrid approach as proposed in the application. Although the EPI technical committee (August 19, 2014) endorsed the recommendation by the HPV coordination committee to adopt the hybrid approach, the NCC called for more discussion on other alternatives that could be more feasible and sustainable (September 4, 2014). A second NCC meeting (September 30, 2014) recommended that HPV vaccine be integrated into routine immunization and requested the EPI technical committee to further discuss this recommendation. The EPI technical meeting (October 28, 2014) agreed that HPV vaccine should be integrated into the routine EPI system which is facility-based with an outreach component.

We can't sustain going to schools so we should only deliver at health facilities. But we realized this would be complicated. (KII, partner organization)

However, the best model should be to integrate HPV into the routine immunization activities for sustainability purposes. (KII, MOH)

The country is now moving forward with a routine immunization-based approach, delivering HPV vaccine at health facilities and outreaches through the routine EPI system and only going to schools that serve as outreach sites. The DG has written to districts to inform them of the HPV vaccine launch and this modified hybrid strategy. The planned delivery strategy for national rollout, as well as the delivery models used in the demonstration sites, are outlined in Table 30.

Table 30: HPV vaccine delivery models used in Uganda

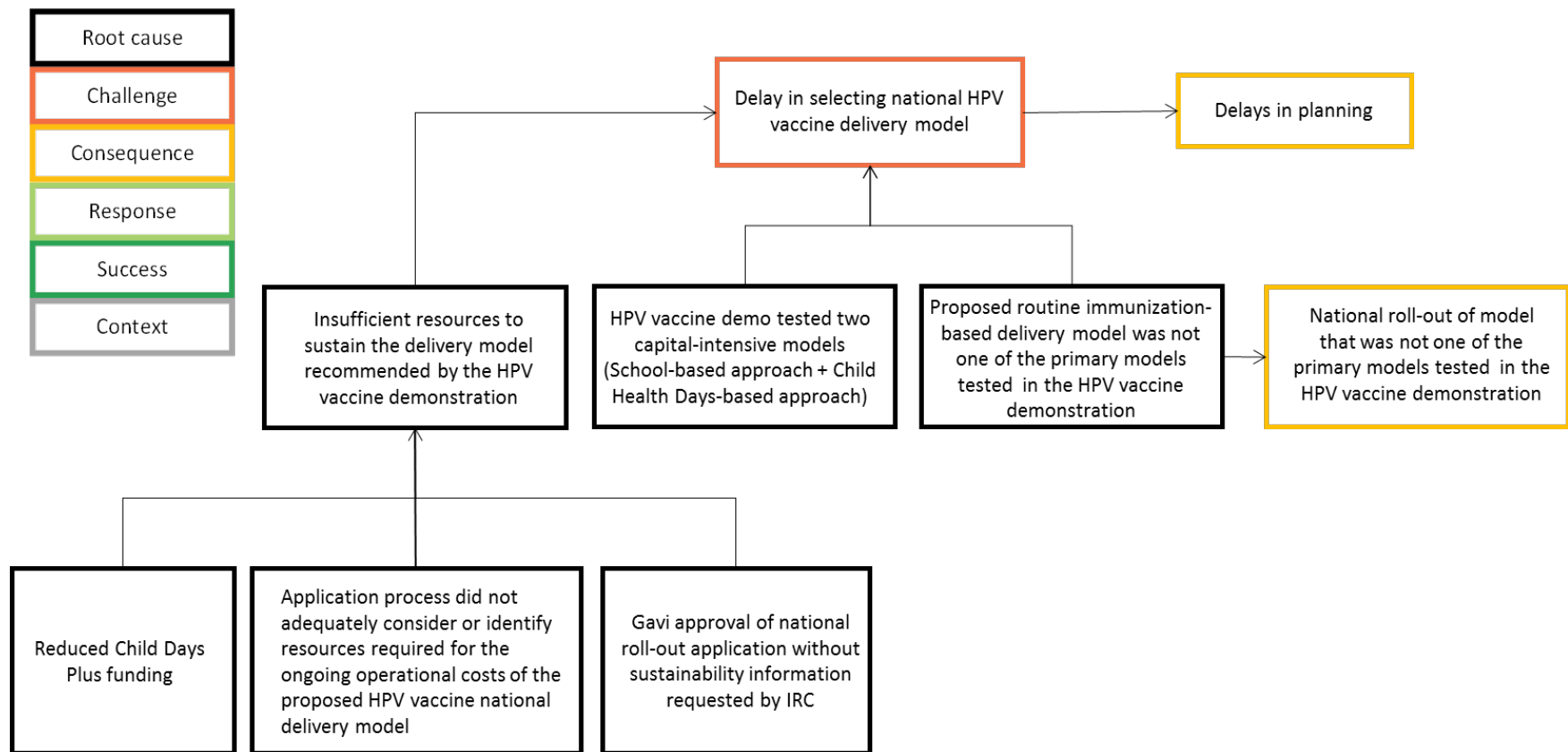
	HPV demonstration project (2008-2009)		Scale-up (2010 to date)	National rollout: Current proposed model
Location	Ibanda District	Nakasongola District	12 additional districts	All districts
HPV Delivery Model	School-based approach (selection by grade)	Child Days Plus-based approach (selection by age)	Hybrid approach (selection by grade)	Routine immunization-based approach (selection by grade)
Description	Health workers visited all schools within the catchment area in June, July, and October to deliver	HPV vaccine doses one and three were delivered in schools during the biannual Child Health Days-plus	Combination of the two piloted delivery models ("hybrid"). HPV vaccine doses one and three were	HPV vaccine will be integrated into routine immunization. Map out all schools within catchment area of each health facility.

<p>three doses of HPV vaccine. Girls were identified based on school grade (Primary 5).</p> <p>Out-of-school girls aged 10 years were eligible. Out-of-school girls were vaccinated either through community outreaches or at health facilities. Out-of-school girls were identified and mobilized by village health teams to come to outreach posts.</p>	<p>(CHDP) in April and November. The second dose was delivered through a stand-alone outreach in schools and outreach posts outside of CHDP months. Girls were identified by age (10 years old).</p> <p>Out-of-school girls aged 10 years were eligible. Out-of-school girls were vaccinated either through community outreaches or at health facilities. Out-of-school girls were identified and mobilized by village health teams to come to outreach posts.</p>	<p>delivered in schools during the biannual CHDP. The second dose was delivered as a stand-alone school visit program. All girls in primary 4 irrespective of age were targeted.</p> <p>Out-of-school girls aged 10 years were eligible. Out-of-school girls were vaccinated either through community outreaches or at health facilities.</p>	<p>Schools close to facilities will take the eligible girls to health facility during static immunization days. Schools far away will visit the nearest outreach posts. Health facilities will draw up a program/schedule for all schools within their catchment area. Health workers will only visit schools that act as venues for outreach sessions. All girls in primary 4, irrespective of age, will be targeted.</p> <p>The out-of-school girls aged 10 years are eligible and will attend static clinics or outreaches depending on their convenience.</p>
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The HPV vaccine national introduction guidelines specify that the country “have demonstrated ability to deliver a complete multi-dose series of vaccines to at least 50% of a one-year cohort...using strategies similar to those proposed for national HPV vaccine delivery.”³⁴ According to one key informant, the MOH and country-level partners do not consider the revised strategy to constitute a change in the approach outlined in the original application, because that application also included delivering vaccines at health facilities, schools, and outreach visits. However, the guidelines do not clearly define what is meant by “similar” strategies. By what criteria will Gavi assess whether the revised strategy is similar enough?

It is important also to note that the discussions on alternative vaccine delivery strategies have taken considerable time (two months), during which the government and country-level partners would otherwise have been planning and preparing for HPV vaccine introduction. While sustainability was ultimately addressed by the government and country-level partners, the process of doing so was inefficient partly due to missed opportunities in the design of the application form and the inadequate attention paid in the IRC review. As part of the Gavi FCE, we will continue to track the planning process and national implementation of HPV vaccine in Uganda.

Figure 53: Root cause analysis of delays in selecting HPV vaccine delivery model



Recommendations

- 1. Acknowledging that HPV vaccine targets a different age group than other routine vaccines, country governments, partners, and Gavi should more comprehensively consider the costs and plan for sustainability of the chosen national delivery strategy. As this is a specific criterion of Gavi's previous and new application guidelines, it is essential that this be included in the application materials and could be ensured by incorporating a section in the application template dedicated to the costing and planning for ongoing vaccine delivery. This information should be carefully reviewed by the IRC and Gavi Secretariat.**

The costs and sustainability of delivery of the HPV vaccine are likely to be above and beyond those of other new vaccines given the very different target population from routine EPI. The HPV vaccine demonstration projects are designed to assess the cost and feasibility of delivery; however, in the case of Uganda, our findings suggest that the cost information and sustainability considerations were not fully translated into the planning process prior to the Gavi application and approval for the national introduction of HPV vaccine. The importance of carefully and comprehensively assessing the resources required and financial sustainability as part of the application and approval process is essential and is clearly identified as a criterion for application. We recommend that a specific section of the application template for HPV vaccine national introduction is devoted to this financial sustainability analysis and that it is subject to careful review by the country's ICC, the IRC, and the Gavi Secretariat.

- 2. MOHs, partners, and Gavi should increase efforts to integrate the Ministry of Finance into all immunization-related partnerships and the Ministry of Education for HPV-specific partnerships.**

While the signature of the Ministry of Finance is a requirement for all Gavi applications (and Ministry of Education for HPV vaccine applications), this evaluation and previous studies^{30,32,33} have observed very limited participation of MOF stakeholders during decision-making and planning processes. Integrating the MOF (and MOE for HPV vaccine-specific partnerships and processes) into relevant decision-making and planning processes will improve the coordination of activities between partners and may ensure that feasibility, sustainability, and ongoing financial resources required for new vaccine introductions are considered. Ongoing partnership mapping as part of the FCE will help to monitor progress on this front; however, without changes in formal procedures or institutional rules, it is questionable whether the MOF will become more involved at the earlier planning stages.

- 3. Country governments and partners when designing HPV vaccine demonstration projects should, where feasible, consider including different delivery models that vary in the resources required to implement them. For example, demonstration projects could test whether a lower-cost option of integrating HPV vaccination as part of the routine EPI delivery system is effective.**

The choice of delivery model for the national rollout in Uganda was informed by the HPV vaccine demonstration project. The subsequent review by the MOH, however, determined that this model is unlikely to be feasible from a financial and sustainability perspective. Although an alternative model

based on routine EPI has been discussed, this has not been tested in the demonstration districts in Uganda. Based on this finding, we recommend that HPV vaccine demonstration projects consider assessing different delivery models with varying resource needs, including the integration of HPV vaccination as part of the routine EPI delivery system.

Robustness of finding

Finding	Ranking	Rationale
Key steps in the application process failed to account for the feasibility, sustainability, and ongoing financial resources required for the chosen and tested HPV vaccine delivery model (a combination of school-based and campaign-based delivery) for national introduction. These failures include lack of participation in the application development process on the part of key partners who could have provided this financial perspective, and failure of the Independent Review Committee (IRC) review process to ensure that this information was provided prior to approval of the application. This led to a switch to a delivery model based on routine EPI that was not one of the primary models tested as part of the HPV vaccine demonstration project in Uganda.	B	Multiple documents (the HPV vaccine application, HPAC meeting minutes, and the HPV vaccine introduction plan 2013), did not contain evidence that the financial sustainability of delivering HPV vaccine was adequately assessed at the time of application. However, as the application process occurred some time ago, this has led to lower-quality information from key informants due to the potential for recall bias. There is an element of perception in the finding, as we are considering the extent to which feasibility and sustainability were taken into account.

Finding 2

Lessons learned from the introduction of PCV led to the Uganda National Expanded Programme on Immunisation (UNEPI) and partners initiating the preparatory phase for the national HPV vaccine introduction earlier than past vaccine introductions. However, there was uncertainty among in-country stakeholders as to when the Vaccine Introduction Grant (VIG) funds would arrive in country to cover the costs of the preparatory activities. This is the result of a mismatch in the understanding of the procedures and timeline for the disbursement of the HPV vaccine introduction grant between the Gavi Secretariat, UNEPI, and partners.

As noted above, the government of Uganda's application for the national HPV vaccine introduction was approved by Gavi in March 2014. Based on the country's previous experience with PCV introduction and the challenges and delays in the implementation process, a key lesson was that the MOH and country-level partners should begin the planning process early for future new vaccine introductions. Our evaluation found that the MOH and country-level partners initiated the planning process for HPV vaccine in May 2014, shortly after Gavi approval, which included the establishment of a special committee to coordinate HPV vaccine introduction.

PCV planning was not well done and plans were not executed on time. We should not face the same bottlenecks with HPV. We should spend more time in planning for HPV introduction so that implementation is smoother. (KII, partner organization)

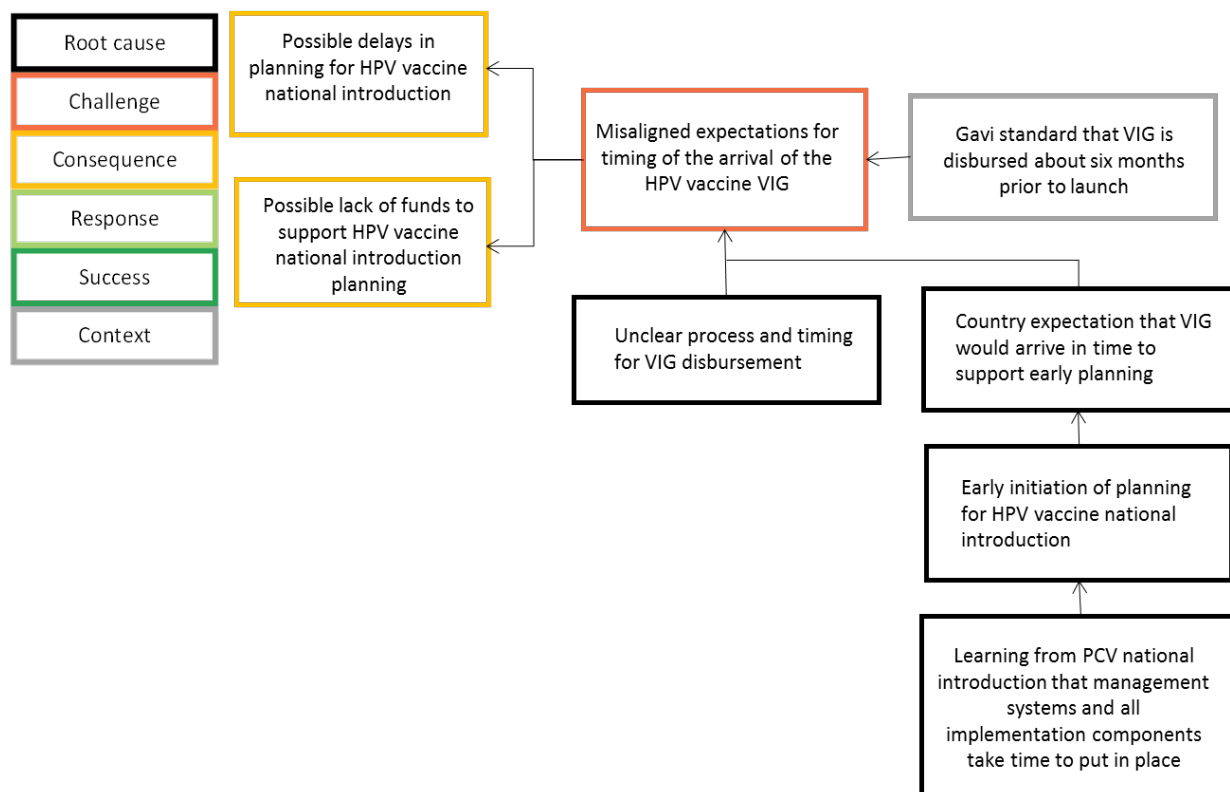
Although the MOH and country-level partners began the planning process early, there was uncertainty as to when the vaccine introduction grant (VIG) would be available to support preparatory activities. Release of the VIG is conditional on meeting some specific requirements, including the submission of audited financial reports for other Gavi funds (PCV VIG, ISS, and HSS), and financial statements. Our findings suggest that the MOH and country-level partners do not have a consistent understanding of the VIG disbursement process, as different stakeholders cited different processes. Some interviewees thought that the government needs to requisition for money from Gavi through a written letter, whereas others thought that the MOH just needed to send an account for funds transfer to Gavi.

Following submission [of the Gavi application], the DG is supposed to write to Gavi informing them about the country's readiness and planned introduction dates. (KII, partner organization)

Gavi recently requested MOH to confirm account details and to revise the budget as per their format. These were sent in September. MOH is waiting for their communication. (KII, MOH)

The VIG was disbursed by Gavi to the government of Uganda on November 20, 2014. This is consistent with our understanding that the usual window for disbursement of the VIG by Gavi is approximately six months prior to the launch date, which was planned for April 2015. However, there appeared to be a lack of communication between the MOH and Gavi regarding the timing of the VIG. The HPV vaccine decision letter from Gavi to the Government of Uganda did not specify exactly when the VIG would arrive, only that it was payable in 2014. Before confirmation of the VIG disbursement, one key informant commented: *The VIG was expected to arrive before the end of this year, but now it may go into next year. We asked the DG and EPI manager to directly follow up [on the timing of the VIG] with Gavi. (KII, partner organization)*

Our findings suggest that this mismatch in understanding between the government and Gavi on the timing of the VIG arrival is in part due to a lack of a formal process and absence of guidelines around requests for the disbursement of the VIG. It is important to note that the lack of guidelines and understanding around the VIG disbursement process is also a challenge the Gavi FCE identified as part of the evaluation of the PCV introduction in 2013.¹²

Figure 54: Root cause analysis of progress in HPV vaccine planning and preparation

Recommendations

1. **The Gavi Secretariat should establish a formal process for requesting vaccine introduction grants which should include details on the timing of disbursement.**

As noted above, our findings suggest that part of the misalignment in expectations for timing of the HPV vaccine VIG in Uganda is due to an absence of formal guidance on the timing and process of requesting disbursement. We recommend that the Gavi Secretariat establish a formal process for requesting the VIG that would allow countries to indicate the desired timing (including a rationale) for disbursement. The Gavi Secretariat should also establish a formalized mechanism for communicating this process in writing to country governments; for example, this process could be articulated in the decision letter at the time the application is approved.

Robustness of finding

Finding	Ranking	Rationale
Lessons learned from the introduction of PCV led to the Uganda National Expanded Programme on Immunisation (UNEPI) and partners initiating the preparatory phase for the national HPV vaccine introduction earlier than past vaccine introductions. However, there was uncertainty among in-country stakeholders as to when the Vaccine Introduction Grant (VIG) funds would arrive in country to cover the costs of the preparatory activities. This is the result of a mismatch in the understanding of the procedures and timeline for the disbursement of the HPV vaccine introduction grant between the Gavi Secretariat, UNEPI, and partners. .	C	The evaluation team were unable to identify a documented process in place for the disbursement of the VIG. The understanding of the process among stakeholders is more perception-based since it is their perceptions of the process. High quality data from a few key informants mentioned different processes, but there are limited data for triangulation.

Health system strengthening and immunization services support

Summary of progress

The government of Uganda was approved for Gavi Immunization Services Support (ISS) cash support in 2000 for US\$9,230,520 over 2001-2004. However, in mid-2006 the Gavi Secretariat suspended cash transfers to the Government of Uganda following misuse of the funds. At this point US\$6,581,000 (71% of the total approved ISS funds) had been disbursed to the country government, and the remainder (US\$2,649,520) was disbursed in 2013, after Gavi lifted the suspension on cash transfers. Meanwhile, the Government of Uganda was also approved for Health system strengthening (HSS) cash support in November 2007 for US\$19,242,000 over three financial years (January 2008 to June 2010). Although the funds were approved in 2007, due to the suspension on cash transfers HSS funds were not disbursed to the country government until 2012. At this point the activities initially budgeted for were outdated, so the funds required reprogramming. An HSS reprogrammed proposal was submitted in February 2014 and approved by Gavi in March 2014. The country government is awaiting the disbursement of the second tranche of HSS funds.

Figure 55: Summary of country progress

Milestone heading
<i>Progress and successes</i>
<i>Challenges and responses</i>
Critical bottlenecks to immunization coverage are identified
<ul style="list-style-type: none"> - Prior to HSS reprogramming (2014), extensive consultations were made with all relevant decision-making bodies of MOH including HPAC and senior management. - A review was made to assess progress made since 2007 when the original proposal was submitted. It was on the basis of this review that the critical bottlenecks and responses were either maintained or removed from the reprogrammed proposal

- Critical bottlenecks included in the HSS 2014 reprogramming:
 - o Lack of staff accommodation in peripheral districts
 - o Inadequate transport means for community outreaches
 - o Inadequate cold-chain space in facilities
 - o Lack of community participation in health care delivery
 - o Inadequate capacity of the private sector to deliver immunizations and other child health services

Appropriate responses to address bottlenecks are identified/developed

- Responses were reconsidered and discussed during the HSS reprogramming process. Some of the changes made included abandoning the idea of constructing six regional hubs for vaccine storage. This was replaced with strengthening the capacity to distribute vaccines country-wide within 48 hours by procuring more vaccine distribution trucks
- Responses included in the HSS 2014 reprogramming:
 - o Improve the delivery of immunization through provision of staff accommodation in selected districts plus a significant increase in peripheral, district and facility level transport and storage capacity
 - o Support the participation of communities in health care delivery and decision-making through scaling up of the establishment and training of village health teams
 - o Strengthen the capacity of the private sector to deliver immunizations and other child health services by equipping them and training health workers in the private sector

Adequate plans to facilitate implementation are developed

- A monitoring and evaluation plan was developed for the reprogrammed HSS proposal.

Successful application to Gavi for funding	
<ul style="list-style-type: none"> - ISS proposal was approved in 2000. - HSS proposal was submitted and approved in 2007. - Reprogrammed proposal was submitted in February 2014 and approved in March 2014. 	
Sufficient amount of Gavi's HSS funding is secured in time	
<ul style="list-style-type: none"> - Gavi committed US\$9,230,520 for ISS for 2001-2004. - Gavi committed US\$19,242,000 for HSS in June 2012 for the program years 2011-2013. 	
Plans for implementation are updated/reprogrammed	
<ul style="list-style-type: none"> - Given the time lag between approval of the grant (2007) and actual disbursement (2013), a reprogrammed plan was submitted to Gavi seeking to update activities to reflect progress made since 2007. - HSS reprogrammed proposal was submitted in February 2014 and approved in March 2014. 	<ul style="list-style-type: none"> - Most people involved in the reprogramming process were new to UNEPI. They had not participated in the original application (2007), thus tracing for documents and key people with relevant information was challenging. This delayed the reprogramming process.
Sufficient funds are distributed to designated entities	
<ul style="list-style-type: none"> - An initial HSS disbursement of US\$4.4 million was made in June 2013. - US\$2.65M ISS funds were disbursed to the government of Uganda in 2013, plus the GOU was authorized to use US\$818,424 that had been recovered and replenished by the GOU as part of the misused funds which had culminated in termination of Gavi support in 2007. Thus, a total of US\$3.47M funds were available for ISS in 2013. - For ISS funds: US\$637,598 was spent in 2013, leaving a balance of US\$2.8M to carry over to 2014. As of September 30, 2014 ~US\$0.5M had been disbursed to districts in two rounds. Approximately US\$2.3M is unutilized, and the grant period ran up to December 31, 2014. 	<ul style="list-style-type: none"> - There was a large time lag between HSS application approval (2007) and initial disbursement (2013). - Delayed accountability from districts for ISS funds. - Some districts (e.g., Sheema) reported that they had not budgeted for ISS funds and thus had to go through the process of presenting a supplementary budget to the district council, which takes time and delayed access to the funds. - The reason for this bottleneck is that districts were not aware that ISS funds would be sent to them. This depicts poor communication between the center and sub national entities. - No accountability guidelines were provided to districts by MOH for ISS funds. - Slow utilization of ISS and HSS funds for procurement due to Uganda's bureaucratic procurement process
The plans are implemented in a timely and comprehensive fashion	

- | | |
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| <ul style="list-style-type: none"> - Procurement irregularities in the PPDA process were identified by the Gavi Secretariat. - The Minister of Health requested Gavi explore other procurement options. Gavi proposed to use other agencies like UNICEF, JSI and CRS to conduct the procurement and do civil works. - MOH sent original specifications of the items needed and the costing estimates to UNICEF mid-July. - In August 2014 NMS prepared the quotation for the central vaccine store to be sent to JSI. UNICEF sent quotations in September and together with the Gavi Secretariat developed a tripartite agreement which was signed by Gavi in October 2014 and by UNICEF in November 2014. The funds were immediately transferred to UNICEF for procurement. | <ul style="list-style-type: none"> - Slow implementation of HSS activities due to Uganda's Public Procurement & Disposal of Public Assets (PPDA) procurement process and additional Gavi requirement that each step be signed off by the Technical Assistance group (Edes & Associates). |
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Analysis of major challenges and successes

Two key findings have emerged in relation to HSS and ISS funds. First, there has been slow utilization of ISS funds at the district level due to the integrated financial management system (IFMS), poor communication between national and subnational levels, and a lack of ISS guidelines. Second, both ISS and HSS implementation were delayed by the long time period for procurement due to Uganda's bureaucratic procurement process, the need to reprogram (for HSS), and the long time to shift procurement out of the GOU to other agencies.

Finding 1

Challenges with the integrated financial management system (IFMS), poor communication between national and subnational levels, non-integration of ISS into the district planning cycle, and a lack of guidelines for districts on how to spend and account for ISS funds have led to slow utilization of ISS funds in Uganda. Notably, the Ministry of Health (MOH) has addressed these challenges; they sent advance communication to districts to notify them of future ISS disbursements and provided guidelines detailing how these funds were to be utilized and accounted for.

Upon signing the Memorandum of Understanding in 2012, Gavi committed US\$2,649,520 for ISS. Gavi also authorized the GOU to utilize US\$818,424 that had been recovered and replenished by the GOU as part of the misused funds which had culminated in termination of Gavi support in 2007. Of a total US\$3.47 million in ISS funds, approximately US\$0.5 million has been disbursed and utilized at the subnational level as of September 30, 2013.

The slow utilization of ISS funds has been due to three main underlying factors. The first root cause is challenges with the integrated financial management system (IFMS). The government of Uganda began

implementing IFMS in 2003,³⁶ and the MOH transitioned to IFMS in 2011. The Gavi FCE 2013 Annual Report¹² highlighted challenges of IFMS in the introduction of PCV10 last year, and there have been continued challenges at the district level in 2014. Moreover, the system is designed to require sign-off from multiple district officials in a multi-step process. Funds are sent from the national level to the district general account, which holds all district funds. After determining which funds belong to health, it is incumbent upon the district accountant to alert the DHO that funds have arrived. Then the DHO makes a requisition, which is first signed off by the Chief Finance Officer and later the Chief Administrative Officer (CAO). In addition, account numbers must be changed each year; this process was particularly slow for new districts. Although the IFMS processes are designed to improve accountability, they may also lead to delays in accessing the funds, especially if these officers are not available in the districts. For example, one district could not access their funds while the CAO was on vacation for two weeks. This is compounded by poor communication between accounts officials in some districts to relay to the DHO's office when funds have arrived via IFMS, how the sign-off process should advance, when the funds are available to use, and how they should be used. Although there are benefits to IFMS in creating transparency and including checks and balances, there have been operational difficulties in using the system at the district level.

The introduction of IFMS ... has only solved the problem of accountability and record-keeping, but [it] does not facilitate faster transfers for payment and spending by other departments. (KII, subnational level)

The second root cause is insufficient communication from the national to subnational level, resulting in delayed planning for use of ISS funds at the district level. Among the five districts interviewed by the FCE team in early 2014, four districts were unaware of the availability of ISS funds. District officials did not know that they would receive ISS funds, so the funds had not been included in their work plans or budgets for the 2013/2014 financial year. This was a communication issue at the core: the MOH did not communicate to districts that they would receive ISS funds. Moreover, when the actual funds had been disbursed to districts, the MOH also did not communicate with the district health officers to alert them of the disbursement.

Even when money was sent to us, we took more than a month to know. Money was sent to the general account which receives all other funds to the district so it was difficult to tease out which money belonged to the health sector. (KII, subnational level)

This led to delays in accessing the funds since, upon receipt of ISS funds at the district level, the accounting officers (DHO and CAO) had to submit supplementary budgets to the district councils in accordance with the Local Government Act (the law that governs the functioning of districts under the decentralization system in Uganda). District councils had to approve the supplementary budgets, but given that the district council only meets once every quarter there was a further delay in approval to use the funds. For example, the entire process took up to four months in Sheema district. With advance communication, districts could have included ISS funds in their normal work planning and budgeting process and would not have experienced delays in accessing the funds once they arrived at the district. This is a similar issue to that documented for other countries where Gavi funds are not incorporated into the normal budgeting process.³⁷ Upon learning of the delays that resulted from the lack of communication to districts about the first disbursement of ISS funds, the MOH improved the process by

sending emails to DHOs to alert them that they would be receiving a second and third disbursement of ISS funds.

The third root cause that we identified was a lack of guidelines on use or accountability of ISS funds. Not only were districts unaware that they would receive ISS funds, but when they did receive the first ISS disbursement it was not accompanied by guidelines on how the funds were to be utilized and later accounted for. Key informants at the district level were unclear on how the funds should be used and how to report back to the MOH on their use. We learned from key informants at the district level that funds from other agencies like UNICEF are accompanied by guidelines and accountability templates.

We received money without guidelines. We were not sure on how to spend it. Although MOH later sent a list of activities to be implemented. It was very hard to compile accountabilities from health facilities. (KII, subnational level)

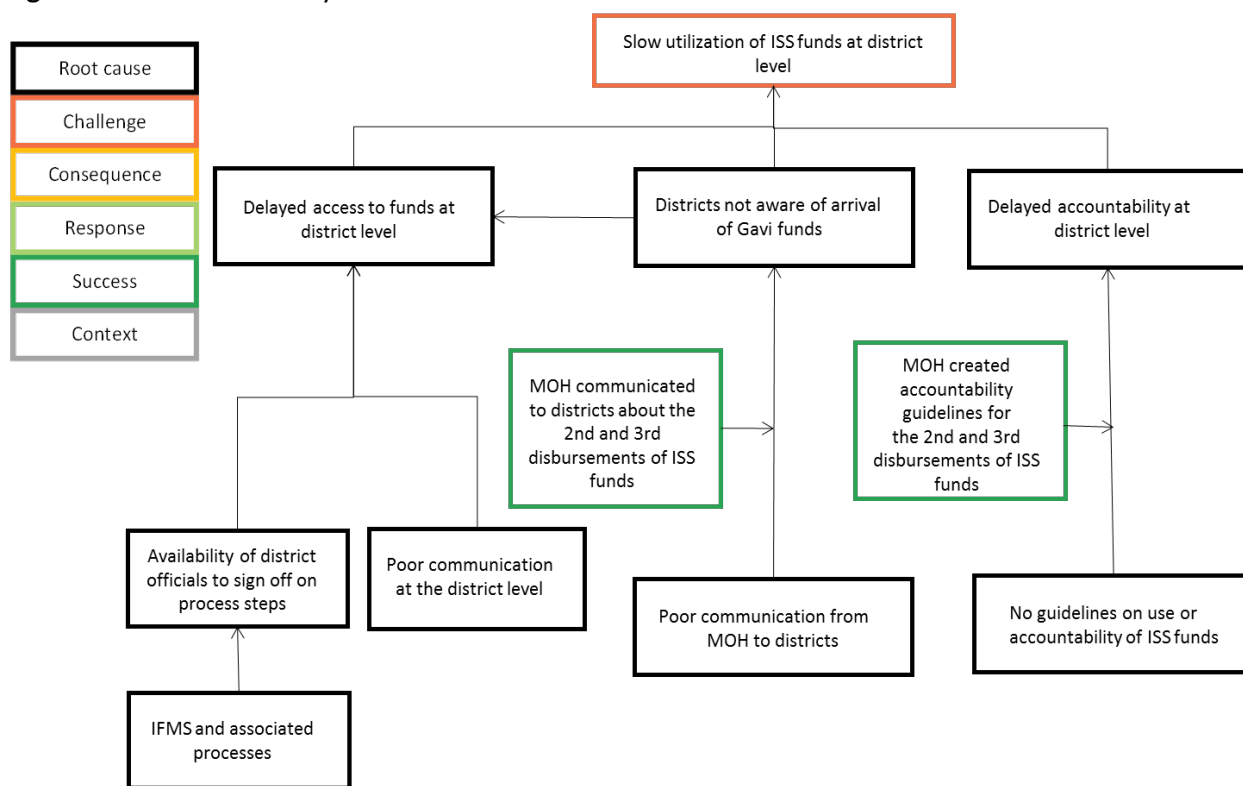
I carried a huge box full of attendance lists and receipts from here to Kampala. This is so risky and hectic. UNICEF has a simple template which we use to account for their funds, it makes work easier. (KII, subnational level)

Districts responded to the lack of guidelines in different ways. For example, some adapted existing guidelines from other agencies (UNICEF), while others used accountability templates for the MOH's primary health care funds, which state that when funds are not accompanied by clear rules for spending, they may be used for other primary health care activities, such as outreach and health worker allowances. The uncertainty around the guidelines resulted in a delay in districts accounting for the use of ISS funds to the MOH, and the MOH would not disburse additional ISS funds to a district until they had accounted for the previous funds received.

As of February 28, 2014, the districts had only submitted accountabilities for 16% of the total ISS funds that had been disbursed. Only 24 of the 112 districts that received Gavi funds during the quarter that ended June 30, 2013, had submitted accountabilities. An additional 22 districts submitted partial accountabilities, and one district accounted for more funds than had been disbursed to it.

The FCE team provided feedback to UNEPI about these findings as part of the routine feedback requested by UNEPI on any actionable findings emerging from the FCE. In response, the MOH sent a circular along with the second and third ISS disbursements (June and October 2014, respectively) detailing how the ISS funds were to be utilized and accounted for.

Figure 56: Root cause analysis for slow utilization of ISS funds at the district level



Robustness of finding

Finding	Ranking	Rationale
Challenges with the integrated financial management system (IFMS), poor communication between national and subnational levels, non-integration of ISS into the district planning cycle, and a lack of guidelines for districts on how to spend and account for ISS funds have led to slow utilization of ISS funds in Uganda. Notably, the Ministry of Health (MOH) has addressed these challenges; they sent advance communication to districts to notify them of future ISS disbursements and provided guidelines detailing how these funds were to be utilized and accounted for.	A	All KIIs at district and national levels provided high-quality data to affirm this finding. Action by the MOH to address the observed challenges confirmed the root cause of a lack of ISS guidelines.

Finding 2

Both HSS and ISS implementation were delayed by the protracted time period required for procurement of equipment and civil works through the Uganda government system and the subsequent transition of procurement to non-governmental partners. These delays were exacerbated by the concurrent reprogramming of HSS funds. The country did not anticipate the time that the procurement transition would take and did not fully realize the implications it would have on spending all HSS funds within the specified support window.

Slow implementation of HSS and some ISS activities has largely been due to delays in procurement. More than 70% of HSS funds and approximately 50% of ISS funds are meant for procurement of equipment and civil works. The public procurement process follows guidelines provided under the Uganda Public Procurement & Disposal of Public Assets (PPDA) law, which is widely considered a slow process, partly because of the numerous checks and balances to ensure transparency and accountability. The PPDA guidelines require a period of open bidding for each piece of equipment to be procured, which can take months. Gavi uses existing country systems whenever possible so all funds for procurement through the GOU must follow the PPDA guidelines. In addition, Gavi required that each procurement stage should be signed off by an external technical assistance group (Edes & Associates), which added another step to the already lengthy process. This measure was put in place as a result of the GOU's history of financial mismanagement of Gavi funds.

When the first disbursement of HSS funds (US\$4.4 million) arrived in June 2013, the MOH initiated procurement of all items under the PPDA. Prior to this, ISS funds had also been used to procure equipment through the PPDA process. However, shortly thereafter procurement irregularities were identified by the Gavi Secretariat and subsequently the Minister of Health reached out to Gavi to request they take over all procurements. Gavi, which is not an implementing agency, consulted with partners and proposed that procurement be transitioned to other non-governmental agencies such as UNICEF, John Snow, Inc. (JSI), and Catholic Relief Services (CRS). Although transferring funds outside of the GOU systems goes against the principle of strengthening country health systems, it was agreed by the GOU and Gavi that this was a necessary shift. Gavi and the GOU worked together to address the issue, and the directive to transfer procurement was made in March 2014 by the Minister of Health.

Although the directive to transfer procurement was made in March 2014, the transition to other agencies has been a lengthy process that has stalled all procurement activities since December 2013. To date there has not been a full transition. The country-based Gavi Coordination Committee was tasked by the Minister of Health to oversee this transition. The committee is composed of key country-level immunization partners: WHO, UNICEF, CSOs, and MOH. The MOH sent the procurement specifications and costing estimates for the items needed to UNICEF in mid-July and Gavi received a quote from the UNICEF supply division in September. In August, the National Medical Stores (NMS) prepared the quotation for the central vaccine store to be sent to JSI. After conducting a quick feasibility assessment JSI declined the offer so, in the words of one key informant, they are now "back to square one" and looking for another source.

During the transition process there were different understanding as to whether an amended MOU between Gavi and the GOU was necessary, which may have delayed the transition process further. Some key informants reported that the decision to transfer HSS funds to other agencies contravened the 2012 MOU between Gavi and the GOU, which stipulated that all Gavi funds must be managed through government structures. Some individuals at country-level thought that the original MOU had to be amended to legalize the transfer of HSS funds to other agencies. This would involve the Government Solicitor General signing off the entire process, thus further delaying the transition, but other stakeholders do not see this as necessary. One key informant suggested that Gavi's Partnership Framework Agreement (PFA) supersedes the MOU to define the relationship between Gavi and the country government. Ultimately, a new tripartite agreement between UNICEF, Gavi and GOU was signed by Gavi in October and by UNICEF in November at which point funds were transferred to UNICEF. According to a key informant at Gavi, the second tranche of HSS funds had been approved in July, but would not be disbursed until the tripartite agreement was in place. Thus, procurement was on hold from December 2013 until funds were transferred to UNICEF for procurement.

Simultaneously, the GOU was going through a lengthy reprogramming process for HSS funds. The funds were originally approved in 2007, but due to the suspension of cash transfers, HSS funds were not disbursed to the GOU until 2012. At that point, some activities initially budgeted for had been implemented by other country-level partners or were no longer relevant, so there was a need to reprogram funds. The 2011 IRC report indicated the need to reprogram HSS funds and this was reiterated in the July 2013 IRC report, which requested a submitted reprogramming proposal by September 2013. It is unclear how well the country government and country-level partners anticipated how long the reprogramming process would take.

Efforts to reprogram the HSS funds were also hampered by a lack of institutional knowledge; most people involved in the reprogramming process were new to UNEPI. They had not participated in the original application (2007), thus tracking documents and key people with relevant information was challenging and delayed the reprogramming process. Despite challenges, the 2013 APR commends the "wide representation of various key stakeholders during the HSS reprogramming in September 2013." However, after the July 2013 IRC request for reprogrammed proposal, it was a full eight months until a proposal was approved by Gavi in March 2014, in the same month the Minister of Health issued a directive to transfer procurement to non-government agencies.

The HSS reprogrammed support was planned to start in July 2014 and last for two years, from 2014 to 2015. During the reprogramming application review, the IRC queried whether the GOU could utilize all the funds in the remaining grant period. Based on our observations, the MOH was confident that the HSS funds could be spent within the given support window and cited a March 2014 status report on progress of HSS by the Gavi project management unit that showed that progress in procuring items had been made under the PPDA. The report stated that many procurement processes had been underway including initiation of transportation purchases (trucks, motor vehicles, motorcycles, and bicycles) and procurement of construction services for the central vaccine stores and 20 district stores.³⁸

The assessment that the MOH would be able to spend out the remaining HSS funds within the fixed two-year window (2014-2015), appears to have been unrealistic, however. This mirrors findings from other countries³⁷ where countries frequently underestimate the time needed to prepare for HSS grant implementation. Only a small fraction of the HSS funds had been spent as of March 2014 (less than 3% of the first tranche received in June 2013) and moreover, all procurement processes in the country were on hold as the MOH awaited guidance from Gavi on new procurement arrangements.

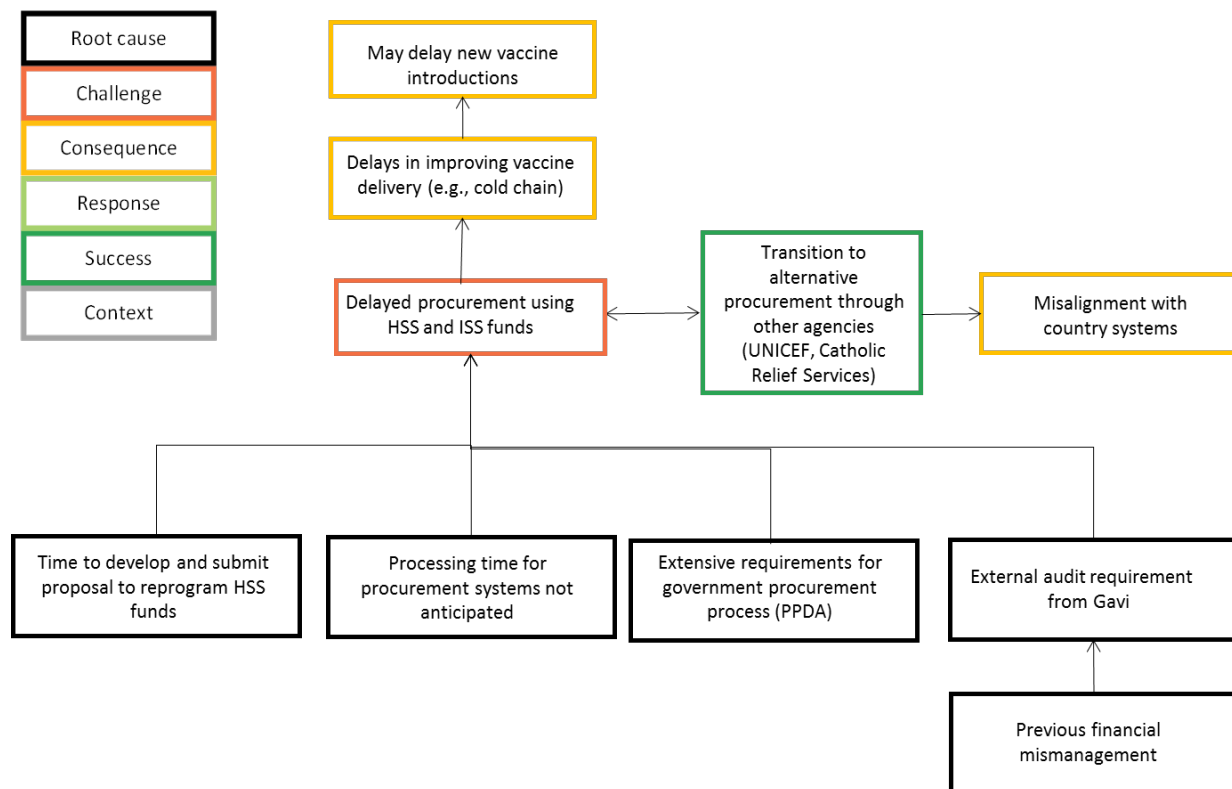
Our observations suggest that the GOU and country-level partners did not adequately anticipate the time it would take to transition procurement to non-government agencies. While evidence from other countries suggests that procurement mechanisms using non-government agents may speed implementation,³⁷ in the case of Uganda, the directive to transition procurement came in March 2014 and funds were not transferred to UNICEF until November 2014. It was unrealistic to think that a full transition to other agencies could occur and all HSS funds could be spent before the end of 2015.

Despite initiating the HSS and ISS procurement process in 2013, little progress has been made toward purchase of cold-chain equipment and construction of staff houses and vaccine stores. These delays are likely to negatively impact the introduction of HPV vaccine and IPV because the MOH had anticipated leveraging the purchases under the ISS and HSS grants to expand the cold-chain storage space for the new vaccines. The FCE team will continue to track how new vaccine introductions have been affected by the delays in HSS and ISS procurement.

Finally, the protracted transition from procurement through the GOU to other agencies highlights the need to balance the intended principles of the HSS/ISS funds with implementation challenges that arise. Gavi HSS support is intended to be country-driven and country-aligned. In principle, the funds should be “consistent with the existing objectives, strategies, and planning cycles of government health sector policy, aligned with government management systems and financial procedures, and reflected in national budgets wherever possible.”⁸ However, in Uganda, the intention to align procurement with the GOU’s management systems and financial procedures had to be carefully weighed against the need to protect Gavi investments in the wake of procurement irregularities. Ultimately, the GOU and Gavi worked together to decide that transitioning procurement to non-governmental agencies was a necessary risk-management strategy.

⁸ <http://www.gavi.org/support/hss/#sthash.Gf9Y26Ck.dpuf>

Figure 57: Root cause analysis for delayed procurement using HSS and ISS funds



Robustness of finding

Finding	Ranking	Rationale
Both HSS and ISS implementation were delayed by the protracted time period required for procurement of equipment and civil works through the Uganda government system and the subsequent transition of procurement to non-governmental partners. These delays were exacerbated by the concurrent reprogramming of HSS funds. The country did not anticipate the time that the procurement transition would take and did not fully realize the implications it would have on spending all HSS funds within the specified support window.	C	There is strong evidence from documents, key informants, and process tracking of activities that shows delays in spending HSS/ISS funds compared to what was planned. The evidence on the root causes of the delays is not as straightforward, although documents and key informants point to the fact that HSS/ISS procurement was delayed due to the PPDA processes and procurement irregularities. There is a lack of clarity around the factors leading to the decision to transition procurement out of the GOU. The lack of anticipation of the time for reprogramming and the procurement transition is implied by observations, sequences of events, and documentation but there is limited

triangulation from key informant interviews.
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Recommendations

Based on these findings, the FCE has developed the following policy recommendations:

- 1. The Uganda MOH should ensure adequate and timely communication to subnational levels about Gavi cash support so that funds are integrated into the district planning process. The MOH should ensure that Gavi cash support is disbursed to the subnational level with accompanying guidelines on use and accountability.**

Once the MOH recognized the need for clear communication to districts about future disbursements of ISS funds and accountability guidelines to accompany the funds, these changes were put in place. The MOH should ensure that advance communication and guidelines are sent to the subnational level for all future disbursements of Gavi cash support. Timely communication will ensure that Gavi funds can be integrated into routine processes, for example the district planning process, in order to streamline the process at the district level and ensure that funds can be accessed and used in a timely manner. This echoes the previous recommendation from the HSS tracking study that Gavi fund disbursement be aligned with planning and budgeting cycles of individual countries³⁷ and extends this to include subnational disbursement processes.

- 2. The application and planning process for HSS (and other new vaccine introductions dependent on HSS funds) should more realistically take into account the time required for government systems (e.g., PPDA, IFMS) and the time needed for reprogramming. Gavi should consider the time required for reprogramming when setting specified support windows.**

In future applications and work plans, the MOH and country-level partners should anticipate and incorporate the time required for government systems. We have observed that the PPDA and the IFMS are intentionally process-heavy systems with many steps, so adequate time for these processes should be built into the plans. Anticipating this timing in the application and planning stage will prevent delays in implementation and unintended consequences for other vaccine introductions that may depend on having procured equipment in place. As with the previous recommendation, this is aligned with a previous recommendation from the HSS tracking study.³⁷

- 3. Country governments, partners, and the Gavi Secretariat should more carefully consider the implications on country alignment and efficiency of deviations from government-based systems of funding and procurement. Decisions to switch to alternate funding channels should further consider the time required to undertake these transitions.**

Although Gavi uses existing country systems and processes (e.g., IFMS, PPDA) whenever possible, there will be times when Gavi, country governments, and/or partners may choose to use an alternate funding channel. As evidenced in other countries, changing procurement mechanisms to other non-government

entities may result in greater efficiency; however, this comes at the cost of misalignment with country processes, a key Gavi principle. The recommendation to more fully consider this balance echoes the recommendation put forth in the HSS tracking study.³⁷ We extend this recommendation to add that country governments, country-level partners, and Gavi should also consider the time and processes required to transition procurement to alternative mechanisms, including putting new agreements in place with the non-governmental agencies. In Uganda, although the transition was determined to be necessary by GOU and Gavi, it is unclear whether the full implications for country alignment and efficiency were considered. We have observed that this transition time has taken one year (since December 2013) and is still ongoing, which has contributed to a delay in procuring essential equipment to improve vaccine delivery.

Pneumococcal conjugate vaccine

As reported in the Gavi FCE annual report 2013,¹² PCV was introduced in April 2013 in the Iganga district in Uganda. Introduction was limited to Iganga because most districts had not yet held training and were deemed not ready for introduction. After the initial launch, PCV was to be rolled out rapidly in a phased manner, countrywide, but questions about training quality led to the country failing a WHO readiness assessment in September 2013. A second readiness assessment followed in December 2013, when the country was confirmed “ready” to introduce PCV. A new shipment of 500,000 doses of PCV10 arrived in Uganda on December 23, 2013 (in addition to the 250,000 doses that were already in-country). All districts were trained and delivering PCV by June 2014. Table 31 summarizes the progress, successes, and challenges by each of the milestone of the TOC for the PCV introduction in Uganda.

Summary of progress

Table 31: Summary of country progress

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Sufficient funding available in time	
<ul style="list-style-type: none"> - Despite the fact that the VIG funds arrived in Uganda in September 2012, the MOH could not access funds until March 2013 (<i>2013 Gavi FCE Report</i>). In response, other agencies stepped in and covered expenses of some planned PCV introduction activities. For example, UNICEF covered the advocacy and social mobilization expenses. Since these activities had been budgeted for in the VIG, this led to US\$385,906 remaining un-utilized. 	<ul style="list-style-type: none"> - Delayed access to the PCV VIG at national level due to the new IFMS
Cold-chain and logistics system is prepared for PCV	
<ul style="list-style-type: none"> - Regular assessments of cold-chain system were done prior to PCV introduction: review and inventory was conducted in 2008, Effective Vaccine Management Assessment (EVMA) 2011 and a second review and inventory in 	

<p>November 2012. In response to the gaps identified through these assessments, procurement of additional cold-chain equipment was done with help from JICA and USAID. MOH also implemented periodic repair and maintenance of fridges up to facility level.</p>	
<p>Adequately skilled health workers are available</p>	
<ul style="list-style-type: none"> - At the beginning of 2014, 94 of 112 districts had trained their health workers at the facility level. Twelve more districts trained in February 2014. The last six districts (Yumbe, Alebatong, Sheema, Kayunga, Gulu, and Hoima) were trained in June. - The national focus on training for PCV after the first failed readiness assessment was a notable success. 	<ul style="list-style-type: none"> - Due to time lag between training of health workers and actual PCV roll out, many health workers had forgotten what had been taught. - Several districts (Gulu, Tororo, and Kayunga) conducted mentorship sessions to reorient health workers, and this was costly since it had not been planned for.
<p>PCV readiness is confirmed</p>	
<ul style="list-style-type: none"> - The first WHO readiness assessment in September 2013 determined that Uganda was not prepared to introduce PCV. - After health worker mentoring and reorientation activities in a number of districts, a second WHO readiness assessment in December 2013 confirmed that the country was prepared to introduce PCV. 	
<p>Sufficient volume of quality vaccine available</p>	
<ul style="list-style-type: none"> - 500,000 doses of PCV vaccine arrived in the country in December 2013 in addition to 250,000 doses that had been shipped prior to the launch. - By June 2014, all 112 districts had PCV. 	<ul style="list-style-type: none"> - Intermittent stocks-outs of PCV have been reported both at district and facility level throughout the country in June, July, and August. - PCV stock-outs are attributed to the backlog of children under 1 who did not receive PCV last year and have carried over to this year, yet vaccine estimates are calculated based on the current birth cohort.
<p>Successful launch of PCV</p>	
<ul style="list-style-type: none"> - PCV was integrated into routine immunization in all 112 districts in June 2014 - PIE was planned for October 2014, but has been rescheduled for January 2015. It will be part of the integrated EPI review that will also involve an in-depth external surveillance review and EPI financial review. 	<ul style="list-style-type: none"> - Delayed roll out due to delayed training of health workers because of delayed disbursement of training money in a subset of districts. - Competing priorities (e.g., the polio campaign planned for December 2014) led to postponement of the scheduled PIE
<p>Routinization of PCV</p>	

- | | |
|--|---|
| <ul style="list-style-type: none"> - The ratio of PCV doses reported to pentavalent doses reported increased to approximately 0.84 by September 2014 (Figure 60), indicating that PCV routinization progressed but was not complete by September. - Using estimates from the HMIS, coverage of PCV vaccination varied by district, ranging from 4% to 109%, reflecting both reporting issues and denominator issues (Figure 61). | <ul style="list-style-type: none"> - It is difficult to differentiate between PCV doses that were not administered and PCV doses which were administered but not reported with HMIS data. - Coverage estimates for PCV are difficult to interpret due to poor/changing data quality in the denominator. |
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Analysis of major challenges

Finding 1

As documented in the 2013 Gavi FCE report, despite plans to rapidly roll out PCV nationwide after the initial PCV launch in one district in April 2013, a WHO readiness assessment in September 2013 determined that the MOH was not prepared to introduce PCV. In the wake of this assessment, stronger in-country partnerships emerged between UNEPI, National Medical Stores (NMS), and other non-governmental partners to mentor and reorient health workers, achieve readiness, and distribute vaccines to all districts, ultimately leading to nationwide rollout.

Although PCV national rollout had been planned to occur in April 2013, only a few districts had conducted training of health workers. The WHO readiness assessment conducted in September 2013 determined that the country was not prepared to introduce PCV.⁹ Following the first readiness assessment, UNEPI made an appeal to all country-level partners to join efforts to make districts ready before the second WHO readiness assessment scheduled for December 2013. Many country-level partners responded: the Pediatric Association of Uganda with support from GlaxoSmithKline (GSK) took the lead in mentorship of health workers across the country; USAID's Maternal and Child Health Integrated Program (MCHIP) and the African Field Epidemiology Network (AFENET) also reoriented health workers in the regions where they operated. The support of country-level partners was instrumental in preparing for the second readiness assessment.

Stronger leadership and resourcefulness by UNEPI also contributed to preparing the country for the second readiness assessment. UNEPI leveraged ongoing immunization activities like SIAs and Child Health Days to pass key PCV messages to health workers and distribute refrigerator stickers. UNEPI also initiated communications to the subnational level, including a circular to all DHOs detailing findings of the readiness assessment and instructions for filling gaps, and text messages to most health workers containing key messages on how to handle PCV.

In addition, there were reports that the PCV doses allocated to Uganda at the global level would be given to other countries in case Uganda was not ready by December 2013. This increased pressure on the country government and country-level partners to increase efforts to make the country ready. The support of country-level partners and action by UNEPI led to a successful outcome of the second WHO

⁹ Refer to Gavi FCE 2013 PCV report for more details¹²

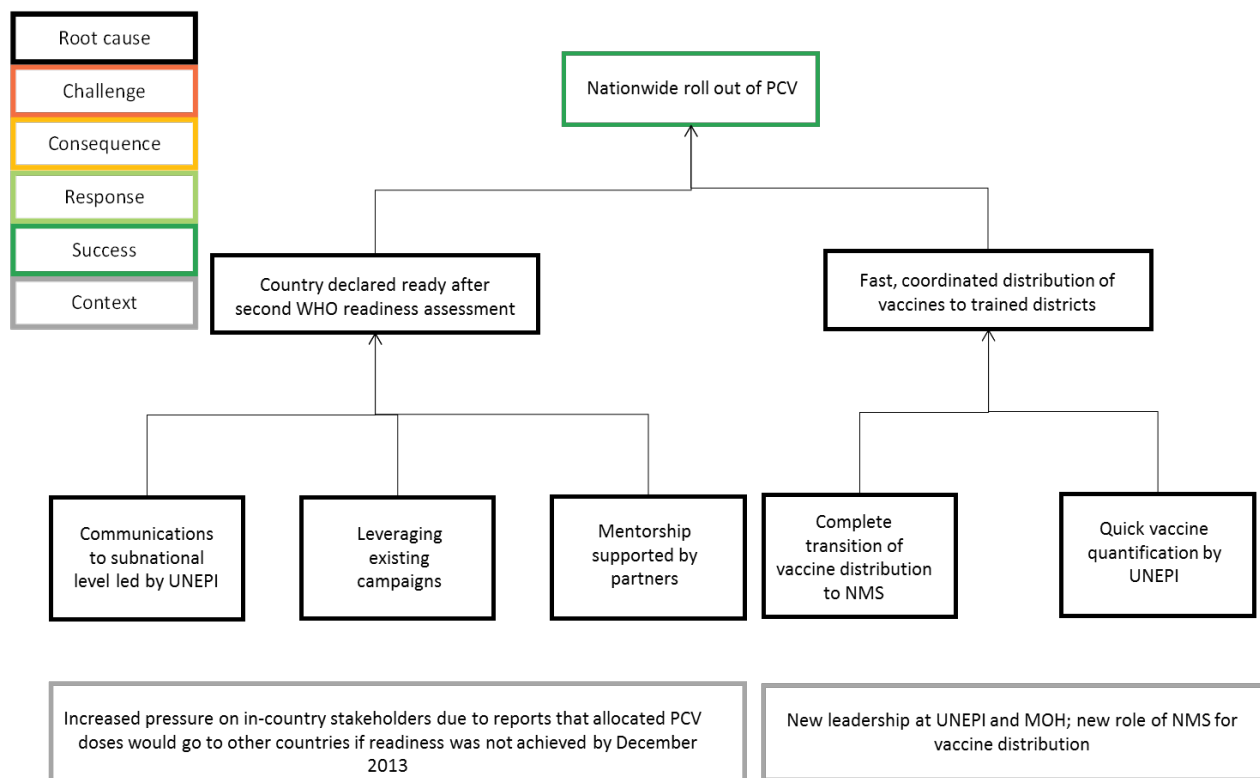
readiness assessment in December 2013, which confirmed that the country was ready for nationwide PCV rollout.

Once readiness was achieved, a faster, coordinated distribution of vaccines followed, leading to expanded rollout of PCV. This was the result of clarity in the roles of NMS and UNEPI and each organization working effectively and efficiently in its respective role. As discussed in the Gavi FCE 2013 report, there were challenges in 2013 resulting from the shift in vaccine distribution responsibility from UNEPI to NMS.¹² However, by the time PCV readiness was achieved in December 2013, there had been a more complete transition of vaccine distribution to NMS. This was in part due to the formation of a steering committee comprised of NMS, UNEPI, and key country-level partners (WHO, UNICEF, and PATH), which was constituted by the Director General of Health Services in October 2013 to clearly define the roles of all parties involved to ensure an efficient transition. The new leadership at UNEPI was also very supportive of the transition to NMS and worked closely with NMS – for example, by including NMS as an active participant in EPI technical meetings.

A new shipment of 500,000 doses of PCV10 arrived in Uganda on December 23, 2013 (in addition to the 250,000 doses that were already in-country). NMS took full responsibility for the distribution of PCV from the national to district levels, and quick quantification by UNEPI of the vaccine requirements per district made this possible. By January 15, 2014, 98 of 112 districts had received PCV, and 68 districts had begun to report PCV to the HMIS.

Another success is the transition from UNEPI to NMS in vaccine management. There were problems in the beginning but the transition has gone well relative to many other countries. This is due a lot to the quality of the people. The new UNEPI manager was very proactive, put this on the top of his priorities, and was very open with NMS. Partners have been very supportive, and placed partners in NMS who know vaccine management. (KII, Gavi)

Figure 58: Root causes analysis for nationwide rollout of PCV



Robustness of finding

Finding	Ranking	Rationale
As documented in the 2013 Gavi FCE report, despite plans to rapidly roll out PCV nationwide after the initial PCV launch in one district in April 2013, a WHO readiness assessment in September 2013 determined that the MOH was not prepared to introduce PCV. In the wake of this assessment, stronger in-country partnerships emerged between UNEPI, National Medical Stores (NMS), and other non-governmental partners to mentor and reorient health workers, achieve readiness, and distribute vaccines to all districts, ultimately leading to nationwide rollout.	A	The rapid timeline in which preparation for the second readiness assessment and subsequent national rollout took place is factual and supported by many sources. While partnership is perception-based, most key informants mentioned that a strong partnership emerged in this period.

Finding 2

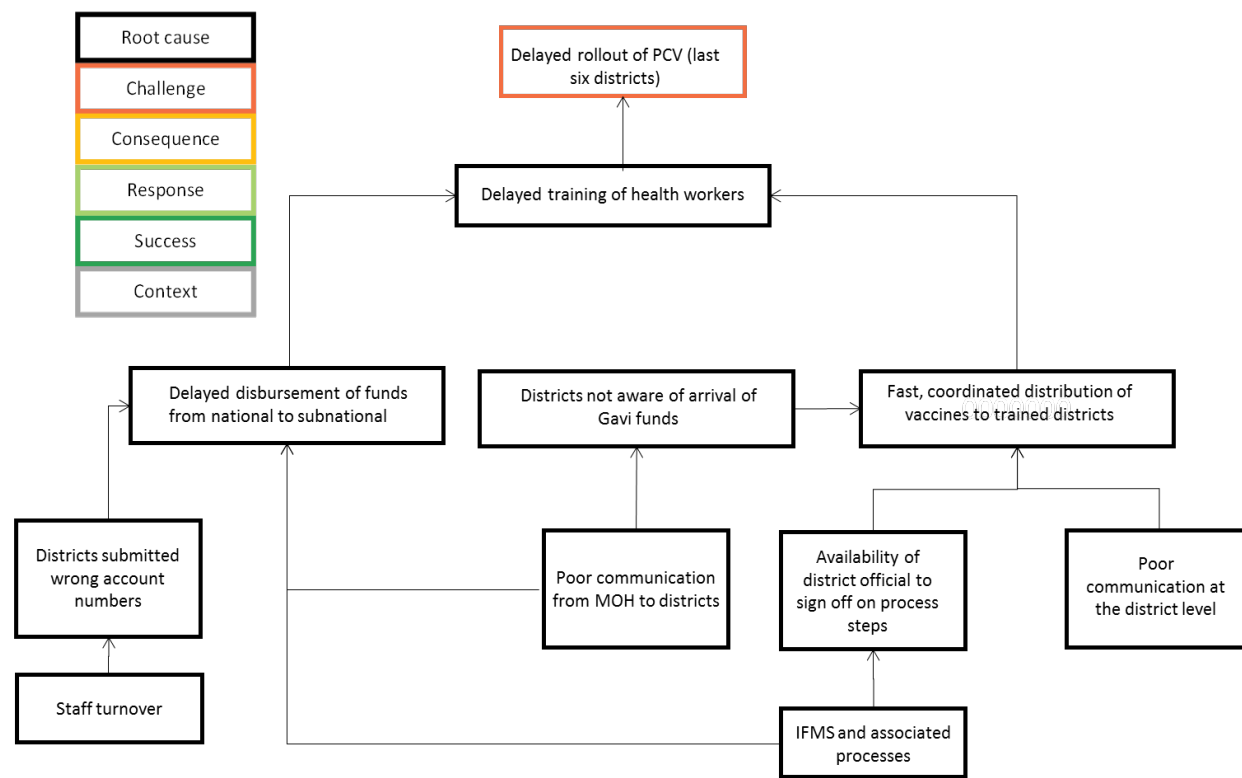
Although the majority of districts received PCV within one month after WHO declared the country ready, a number of districts experienced continued postponements in the introduction of PCV due to delayed training of health workers resulting from delayed access to funds at the district level. The underlying causes of the delays were staff turnover that led to new district staff submitting incorrect account numbers to the national level, the multi-step process of transferring funds from the national to district level through IFMS, and poor communication at various levels.

Although the majority of districts received PCV within a month after WHO declared the country ready, 18 (of 112) districts remained untrained. Twelve of these districts were trained in February 2014, but it was not until June 2014 that the final six districts in the country were trained and began providing PCV. Despite a planned rollout of PCV in April 2013, it took more than one year to achieve nationwide rollout. This delay, particularly in the final six districts, was due to delayed training of health workers in these districts as a result of staff turnover, the new IFMS, and poor communication at various levels.

In all of the final six districts, there was a delay in disbursement of funds from the national to the district level. IFMS requires districts to submit account numbers that are updated every fiscal year in accordance with the Local Government Act. It was reported that all six districts submitted wrong district general account numbers where training money was supposed to be deposited. One district explained that this was due to high staff turnover, as new staff did not know that the account numbers changed each fiscal year. For example, in Sheema district there was a new Chief Administrative Officer, new acting DHO, and new accountants.

Most key informants at the district level reported that it took more than two months for the MOH to inform them the incorrect account number had been provided, but even when the anomaly was discovered and new account numbers were submitted, it took an additional four months for districts to receive money. The underlying problem seemed to be poor communication between the MOH and the districts. There seems to be no formal structure and hierarchy of communication between UNEPI and districts. In fact, each of the affected districts responded differently in the bid to rectify the problem; whereas Sheema district contacted the Minister of State for Health who doubles as the local area Member of Parliament, Gulu district wrote to the Permanent Secretary.

Finally, the same communication and IFMS issues that were discussed in Finding 1 of the HSS/ISS section (p. 178) also apply here. The multi-step process of transferring funds from the national to district level through IFMS, compounded by poor communication between district accounts officials and between the district and national level, delayed access to funds for PCV health worker training at the district level.

Figure 59: Root cause analysis for the delayed rollout of PCV in six districts

Districts began reporting PCV data to the HMIS with some delays as well. In addition to the 68 districts that were reporting PCV data to the HMIS in January 2014, 23 districts began reporting PCV to the HMIS in February. Seven districts delayed reporting to the HMIS until March, four delayed until April, nine delayed until May, and two districts (Kayunga and Sheema) were the last to begin reporting, both reporting their first PCV doses to HMIS in June.

Although nationwide rollout of PCV was achieved in June 2014, the HMIS data suggest that PCV had not become fully routinized as of September 2014. PCV routinization can be measured by comparing the number of reported doses of PCV to the number of reported doses of pentavalent, which is already part of routine EPI delivery. The national PCV-to-pentavalent ratios in Figure 60 demonstrate that PCV delivery increased relative to pentavalent in the first half of 2014 but actually declined in June, July, and August. This figure is based on the HMIS and should be interpreted with caution because of data-quality issues; trends are both influenced by the number of PCV doses being administered and the number of health facilities reporting to the HMIS.

Stock-outs could explain the national-level decline in PCV doses relative to pentavalent between June and August (Figure 60). Eligible children who would have been vaccinated in 2013 either entirely missed the opportunity to be vaccinated or were carried over to 2014. The delays may have contributed to reported PCV stock-outs in some districts in June, July, and August 2014. Several reasons for the stock-outs have been advanced by different stakeholders: some attribute the stock outs to accumulated unvaccinated children from 2013 (carry-over), others said it could have been due to vaccination of children outside the target age group (above 1 year). Finally, other stakeholders mentioned global

shortages. Although we have not yet established the exact cause of the stock outs, it may have set back many districts that had already reported full routinization of PCV (a ratio of one or higher), as seen in Figure 62. The FCE will continue to track the routinization of PCV in 2015 and will assess this further through an ongoing health facility survey and planned household survey.

The PCV dropout percentage (the fraction of children who receive the first dose but do not complete the third dose) exceeded the pentavalent dropout percentage nationally. In September, this fraction was 27% for PCV dropout and only 7% for pentavalent according to the HMIS. The PCV drop out fraction exceeded that of pentavalent in 90 districts in September 2014. Much of the difference in dropout percentage can be attributed to delayed rollout; districts that were still scaling up PCV in or after March cannot be expected to administer as many third doses as first doses in September. Nevertheless, PCV dropout was higher even in districts that had reported full routinization of PCV in February or March, a finding that may relate to previously mentioned stock-outs.

Coverage

According to the HMIS data, national coverage of the third dose of PCV reached 61% in September 2014. Figure 61 shows district-level PCV third-dose coverage in September, based on HMIS data. A number of factors make coverage estimated by HMIS data challenging to interpret. The largest challenge among them is uncertainty related to the denominator (district-level infant population projections), followed by unknown completeness of reporting from all facilities. Many anomalies are clear from the map, including a number of districts with coverage that is greater than 100%, and a few that have coverage of nearly zero. This indicates that alternative sources of data will be required in the short term, at least in supplement to HMIS, to accurately estimate PCV coverage. The household survey planned as part of the Gavi FCE will be an important source of information to verify PCV coverage.

Robustness of finding

Finding	Robustness ranking	Rationale
Although the majority of districts received PCV within one month after WHO declared the country ready, a number of districts experienced continued postponements in the introduction of PCV due to delayed training of health workers resulting from delayed access to funds at the district level. The underlying causes of the delays were staff turnover that led to new district staff submitting incorrect account numbers to the national level, the multi-step process of transferring funds from the national to district level through IFMS, and poor communication at various levels.	A	This finding is largely factual and is supported by KIIs at the national and subnational levels, as well as HMIS data. Although we have noted issues with the quality of the HMIS data, the triangulation with high quality data from multiple KIIs strongly confirms this finding.

Figure 60: Uganda PCV-to-pentavalent ratio, national level

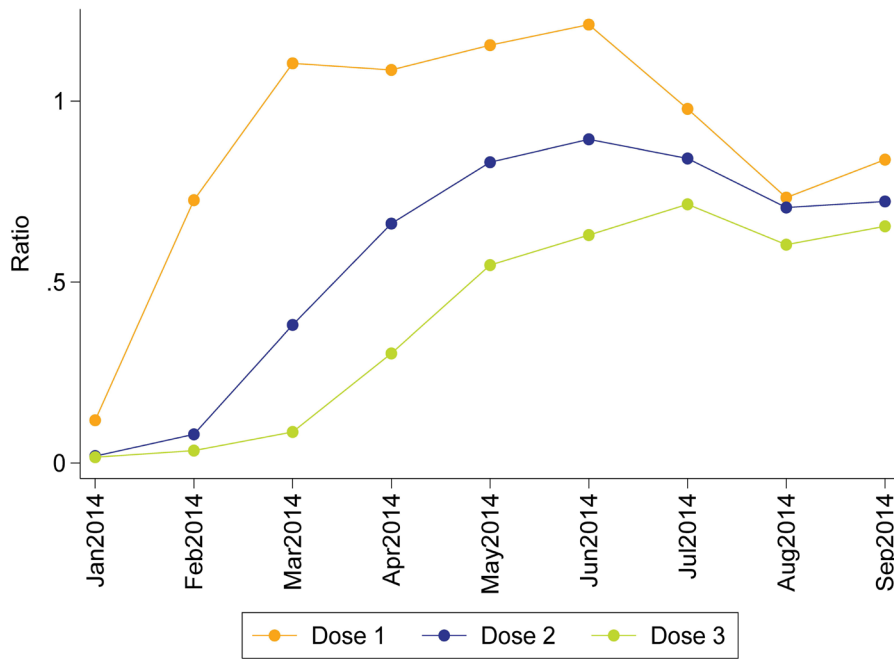


Figure 61: PCV coverage (third dose) computed from HMIS, September 2014 (percent coverage)

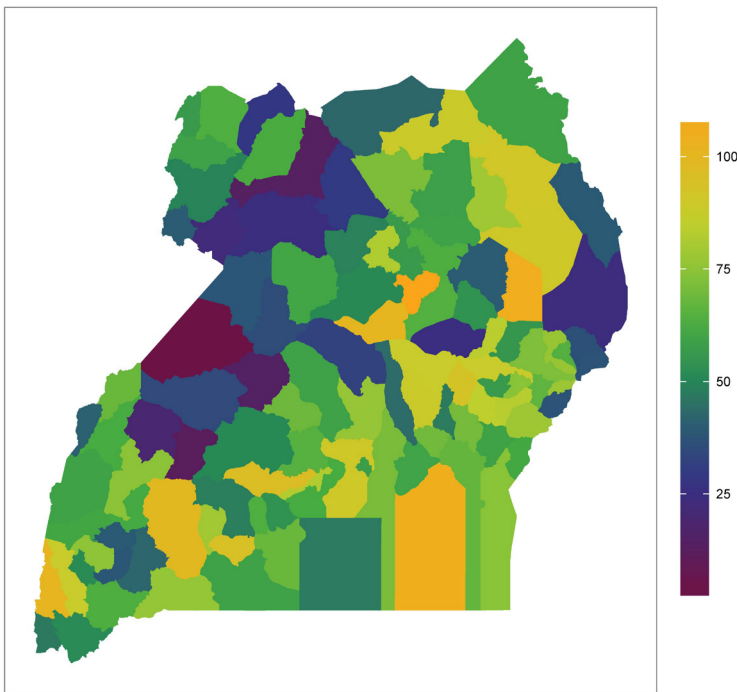
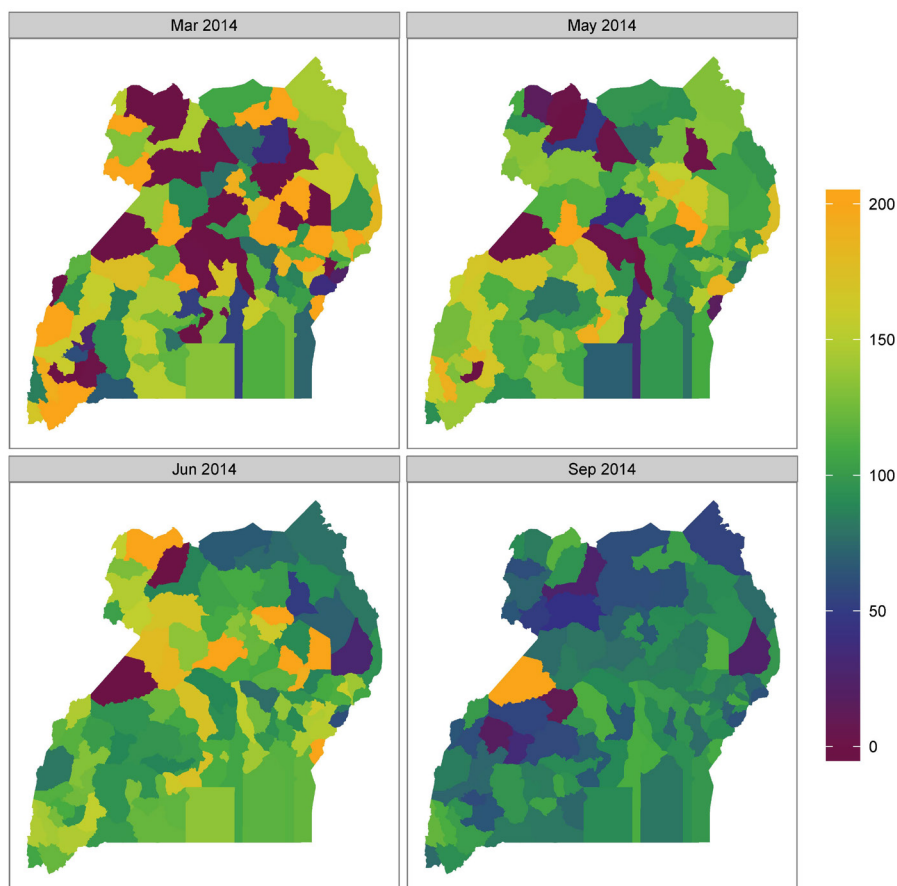


Figure 62: Uganda PCV-to-pentavalent third-dose ratio, district level

Inactivated polio vaccine

Summary of progress

Uganda is one of the countries in the “wild poliovirus importation belt,” a band of countries stretching from West Africa to Central Africa and the Horn of Africa that are recurrently re-infected with poliovirus originating from northern Nigeria. Therefore, though Uganda has not had any recent cases of WPV importation, it remains at risk.

In 2014, the government of Uganda applied for Gavi support for IPV with an introduction date set for May 2015. The application took advantage of the decision by the Gavi Board in 2013 to support the introduction of IPV as part of routine immunization programs. Gavi support for IPV introduction waives a number of application criteria, including co-financing; however, countries must apply for support by June 2015, with introduction targeted by the end of 2015. The FCE team has been tracking the application process, but we have not yet undertaken in-depth process evaluation methods on this stream as it is in the very initial stages in the country.

The decision to apply for IPV was perceived to have been pushed by global partners. Few partners participated in the process to determine whether IPV introduction was programmatically acceptable and feasible, and the application process was largely characterized as not involving many partners.

For example, the decision on IPV characteristics for introduction was led by WHO; in-country players had minimal discussion on this issue. The country would have preferred the hexavalent formulation but was deterred by the cost and the fact that Gavi was not funding this formulation. The fact that Gavi required no co-financing from the government made the decision on financial feasibility straightforward.

The IPV application was submitted to Gavi in May 2014. Gavi approved the application, with comments, in July 2014; UNEPI submitted responses in August 2014. The process of applying for IPV was less time-consuming than other new Gavi vaccine introduction applications and included a more limited set of country-level partners. A small team from UNEPI, WHO, and UNICEF met twice in May 2014 and completed the application.

Unlike other new vaccines, the decision to apply for IPV was based on the recommendation by WHO. The decision to introduce IPV was more of a global initiative toward the Polio Endgame rather than an in-country drive.

The decision to apply for IPV was influenced from global level. I think it is because of this polio endgame to reduce on the polio associated with OPV. (KII, partner organization)

Some of these resolutions are made in the World Health Assembly, so us, [in country stakeholders] have to implement these resolutions. So the pressure comes from the global level. (KII, partner organization)

These comments are consistent with those from global-level key informant who indicated the increased political commitment around IPV at the global level, which was partly attributed to the perception that IPV was more of a joint priority among global partners due to the Polio Endgame Strategic Plan.³⁹

Yes, there have been many more financial resources poured into it, and also more higher-level engagement.... The difference is that [new vaccine introduction] is often seen as a Gavi goal, a Gavi objective. Here, we are seeing it as a joint goal. (global-level KII)

In addition to the global pressure, the decision to apply for IPV was influenced by the limited conditions required for the application compared to other vaccines (e.g., no co-financing or evidence of disease burden required).

The waiver of co-financing and introduction support made it easier to apply for IPV because it was easier to convince the ministry of finance to apply for the programme. IPV is free; why not apply? (KII, MOH)

Furthermore, the application process for IPV involved fewer country-level partners (WHO, UNICEF, CHAI, MACIS, and MOH), especially as compared to the HPV vaccine application process submitted two months earlier (March 2014), which involved several additional partners. With fewer partners involved in the process, the application was perceived as quick and generally easy compared to other applications also because it had fewer application conditions. The IPV application was compiled and submitted in one month while other applications like HPV took three months before final submission to Gavi.

For IPV application, WHO, UNICEF and a few other partners like CHAI took the lead. (KII, partner organization)

The expedited application process, however, also was accompanied by less consultation and partner involvement and discussion.

For IPV application, the partnership was different in that the process was rushed and partner involvement was not really sought. (KII, MACIS)

A partnership did exist for the HPV application process. This partnership differed from the IPV application. The IPV application already had an existing structure in place, and came in as a global push. (Short notice) Further, this application process [IPV] wasn't adequately shared with partners, i.e., it wasn't discussed. (KII, MOH)

National IPV introduction is planned for July 2015. The FCE team will continue to track developments related to the planning and implementation of IPV, as well as the possible consequences of a smaller and less inclusive partnership on implementation success and country ownership.

Cross-stream findings for Uganda

In looking at the findings across the various streams of Gavi support in Uganda, several consistent themes emerge. We elaborate on each of these themes below.

Planning challenges but learning from past experience

Several examples emerged where plans did not provide adequate time for key steps of the implementation process or align with related processes or competing priorities within the country. One of the major bottlenecks hindering the implementation of Gavi funds at district level for both PCV roll out and ISS was the failure to align with district-level planning processes. When ISS and PCV funds were disbursed to districts, they were disbursed off-cycle, meaning they were independent of the annual planning and budgeting process that districts undertake. Supplementary budgets needed to be submitted to district councils and approved before the funds could be used. The time required for this process was not accounted for in the ISS and PCV implementation plans, which contributed to the slow rate of implementation. Similarly, plans for procurement of equipment and civil works under HSS and ISS did not account for the time required to follow the PPDA guidelines and subsequent review and sign-off by Edes & Associates. Both of these processes (IFMS, PPDA) were established and the requirement that they be followed was known to the country government at the time of signing the MOU and reprogramming of cash support.

There is also evidence that the government and country-level partners are learning from past experience regarding the need to begin the planning and implementation process early. Key lessons learned from the PCV introduction process were that planning should begin far in advance of the planned launch date and training of health workers should occur at the same time in all the districts and in close proximity to the launch date. These key lessons learned have been adopted into plans for the national introduction of HPV vaccine, which is planned for April 2014. Planning began early, even before the HPV vaccine VIG arrived, with a coordination committee to oversee HPV vaccine introduction constituted in May 2014 and different subcommittees constituted in August 2014. The HPV vaccine preparatory activities have been discussed in two EPI technical meetings (August 19 and October 28, 2014) and two National Coordination Committees (September 4 and September 30, 2014). Training of health workers on HPV vaccine will begin only after all districts have confirmed receipt of training

logistics and funds. All this is aimed at leveraging the lessons learned from the PCV introduction process to improve the HPV vaccine introduction process.

Misalignment with country processes and systems

Across the streams of support in Uganda, a common theme that this evaluation has is instances of misalignment of the structure of Gavi support with country processes and systems, a finding observed in other countries^{40,41,42} and inconsistent with the principles of the Paris Declaration. One important example is the shift from the GOU PPDA to procurement through an alternative system. A second example is the absence of integration of Gavi ISS funds into the district planning cycle. A third is the Gavi requirement that the GOU submit audited financial reports at the beginning of each calendar year. This was inconsistent with the Uganda financial year system that begins on July 1 and ends June 30. In addition, Gavi wanted the GOU to generate financial reports using a Gavi-specific template yet the IFMS is programmed to generate generic financial reports for all projects/programs. It is important to note that each of these shifts has a rationale behind it, but the implications of these decisions on the alignment with country processes and systems should be carefully considered.

Central capacity and competing priorities

Implementation of Gavi-supported work happens concurrently with the provision of routine immunization services and other immunization initiatives, and UNEPI is the lead agency for carrying out all immunization-related activities in the country. We have observed that the few UNEPI staff are strained by the numerous immunization activities in the country. Gavi-supported work stalls when competing priorities such as periodic mass campaigns require UNEPI's main focus. As was the case with the PCV introduction, the process of planning for HPV vaccine introduction is being overshadowed by the upcoming house-to-house countrywide polio campaign planned for December 2014. A specific example is the NCC meeting held on October 31, 2014, wherein only the polio campaign was discussed despite deliberation on the proposed HPV vaccine delivery model also being on the agenda.

The HPV timelines have been revised thrice due to competing priorities but time is running out and stakeholders need to realize this. The polio campaigns which were scheduled for October were moved to November which realistically means they will be conducted in December. The country intends to introduce the [HPV] vaccine in 2015 however there are so many competing priorities. (KII, partner organization)

This was reflected in partnership interviews, where respondents stated that one core partnership operated to manage most immunization activities. We will continue to track how the polio campaign affects preparation for HPV vaccine introduction. In general, however, we note that implementation plans for Gavi support do not account for competing priorities that the EPI program must also manage.

Emerging partnerships

A noted success in Uganda is the role of an emerging partnership between the country government and other country-level partners who are working together to improve processes and build trust. This is critical given the aforementioned limitation in central planning capacity. A well-coordinated partnership was exhibited during the PCV introduction process after the first readiness assessment by WHO declared the country not ready. The MOH made an appeal during the EPI meeting on October 4, 2013, to all partners to support the country in achieving readiness before the second assessment, which was scheduled for December 2013. In a short time many country-level partners, including the Uganda

Pediatric Association (UPA), Africa Field Epidemiology Network (AFENET), Maternal and Child Health Integrated Program (MCHIP), and Red Cross conducted mentorship sessions for health workers in all regions of the country.

This spirit of coordinated partnership was also observed during the HPV vaccine application process in May-September 2013. The HPV vaccine application process exhibited a dense and well organized partnership, involving many more partners with strong ties and trust (see Annex 11 for full partnership analysis results). The HPV vaccine application process brought on board partners that were particularly new to the typical Gavi application process. These included PATH, Office of the First Lady, and academic institutions like the Cancer Institute-Makerere University. CHAI also played an active role. As a result of leveraging partners' core competencies, the HPV vaccine application process was smooth. The effectiveness of the partnership was also attributed to previous experiences (PCV, polio vaccine, and measles vaccine campaigns) as well as the HPV vaccine demonstration project. While partnerships change somewhat for each stream, the central core seems to be consistent and continually becoming stronger.

However, the Ministries of Finance and Education were not frequently named by respondents as participants in the HPV vaccine application process; this may have led to gaps in budgeting and planning for financial sustainability for HPV vaccine during the application process, as has been suggested for other countries' new vaccine decision-making processes.³⁰

The IPV application did not leverage this growing partnership; fewer partners participated in the IPV application process, and the level of trust was perceived to be lower. Respondents attributed the different structure and nature of the IPV partnership to the "global push" to introduce IPV as well as the shorter application.

Improved communication regarding Gavi policies and processes in country but lack of clarity remains

Communication between Gavi Secretariat and Vaccine Alliance partners and the country government seems to have improved over the last year based on our observations at the joint appraisal mission (April 29, 2014). In addition, we observed that the decision by Gavi to hold in-country meetings to discuss concerns on the Annual Performance Report (APR) was well received by the country government and country-level partners. Perhaps as a result, the process, of compiling and submitting the 2013 APR report was much smoother in comparison to the 2012 APR, which was rejected by Gavi. Despite this forward progress, we also note a continued lack of clarity among the country government and country-level partners with respect to Gavi policies and processes and this often results in delays in planning and/or implementation. For example, the process of disbursement of VIG funds from Gavi is not clear. Most key informants were under the impression that the VIG was delayed, given that planning activities had already begun.

Subnational communication challenges

Findings of this assessment revealed that communication between the national level and districts with regard to both PCV VIG and ISS funds was not timely or comprehensive. Prior to the first ISS disbursement, no communication was sent to districts that ISS funds would be disbursed to districts in the 2013-14 financial year; as a result, most districts had not planned or budgeted for these activities. Even when funds were disbursed, the MOH initially did not provide districts with guidelines on how to

use and account for the funds, which led to delays because districts could not utilize the funds immediately.

At the subnational level, communication challenges were also noted. Districts in Uganda operate through a semi-autonomous decentralized system whereby all funds pass through one district general account whose signatories are the Chief Administrative Officer (CAO) and the Chief Finance Officer (CFO). In one district, we observed that it took two months for the District Health Officer (DHO) to realize that money for immunization had been sent to this account due to poor communication between the responsible departments within the district. The process of accessing the money also requires timely communication and coordination: the DHO must make a requisition for these immunization-specific funds, which then must be approved by both the CFO and the CAO. As these two officers are not always readily available, the process of implementation can be further delayed.

Conclusion

During 2014, the GOU has implemented three Gavi streams of funding: the PCV VIG, the HSS grant, and the ISS grant. Complete nationwide rollout of PCV, achieved in the last remaining districts in June 2014, was an important accomplishment. The country also successfully applied for and received approval for national introduction of IPV and HPV vaccine. The government and country-level partners began preparatory activities in 2014 and plan to roll out the new vaccines in a phased approach in 2015.

As the country government and country-level partners plan to introduce two new vaccines in 2015, they are drawing on learning from past experiences implementing Gavi support. Key lessons learned from the slow PCV introduction process were adopted into plans for the national introduction of HPV vaccine. For example, planning began well before the planned HPV vaccine launch date in April 2014, and training of health workers on HPV vaccine will occur at the same time in all the districts and in close proximity to the launch date to avoid a time lag between the launch and actual nationwide rollout.

However, implementation of Gavi support in Uganda still faces planning challenges. We observed that most plans did not provide adequate time for the implementation processes. For instance, plans for procurement of equipment and civil works under HSS and ISS did not account for the time required to follow the PPDA guidelines and subsequent review and sign off by Edes & Associates. We also note that implementation plans for Gavi support do not account for competing priorities that the EPI program must also manage.

In addition, the evaluation established that there are instances where the structure of Gavi support is misaligned to country processes and systems. For example, Gavi requires that the GOU submit audited financial reports at the beginning of each calendar year, yet the country operates through fiscal years that run from June 30 to July 1.

Positive and negative unintended consequences of Gavi support

One key positive unintended consequence of Gavi support to Uganda is the emergence of a strong and effective partnership of immunization stakeholders; this was reflected both in the support for the country to achieve PCV readiness status and in the HPV vaccine application process. The need to prepare for the second WHO readiness assessment within two months necessitated pulling together resources from several country-level partners; this effort formed a partnership. This strengthened during the development of the HPV vaccine application. As a result of leveraging partners' core competencies, the HPV vaccine application process was smooth. There still remains room for

improvement in the partnership, as evidenced by the earlier inadequate assessment of financial sustainability of the HPV vaccine national introduction.

The increasing role of partners is also reflected in the resource tracking work, with absolute increases in immunization funding from 2010 to 2013 contributed by partners that included AFENET, MCHIP, UNICEF, WHO, PATH, Red Cross Society Uganda, and Sabin Vaccine Institute (Figure 45).

The IPV application process did not leverage this growing partnership. The perceived “global push,” in line with the Global Eradication Strategic Plan, was encouraged by the design of Gavi support, with incentives like a co-financing waiver and a shorter application. Although this contributed to a faster and smoother application process, fewer partners participated in the IPV application process and the level of trust was perceived to be lower. This may have had the unintended consequence of reducing the country ownership of IPV introduction. We will continue to track these partnerships during the 2015 FCE evaluation period.

Furthermore, we observed improvement in communication between Gavi Secretariat and Vaccine Alliance partners and the country during the 2014 evaluation period. This may have been an unintended positive consequence of Gavi’s decision to hold in-country meetings to discuss concerns on the Annual Performance Report.

One key negative unintended consequence noted was the unanticipated delays in HSS implementation caused by procurement transfer from HSS from MOH to other agencies. This transition met several unanticipated challenges, including withdrawal of one of the agencies (JSI) that was requested to construct the central and district vaccine stores. Furthermore, non-governmental agencies will charge a 10% fund management fee; this fee was not originally budgeted for in the HSS reprogrammed proposal. This may have further negative unintended consequences on the introduction of other new vaccines, notably HPV vaccine and IPV in 2015, since the MOH anticipated leveraging the purchases under the HSS and ISS grants to expand the cold-chain storage space for the new vaccines. The FCE team will continue to track how new vaccine introductions have been affected by the delays in HSS and ISS procurement.

Relatedly, Gavi funds have had the unintended consequence of revealing tension between designing country processes to improve transparency and accountability and the operational difficulties resulting from these slow, multi-step processes. We have observed this tension in both the PPDA process and the IFMS.

Finally, both the government of Uganda and Gavi’s total amount of spending on immunization activities in Uganda grew over the past four years. The total envelope for spending has increased and Gavi has remained the most significant contributor to the EPI program outside of Uganda. Gavi’s support may have catalyzed contribution of funds from the government as well as from other donors. In the 2015 evaluation period, the FCE will monitor this potential positive consequence of Gavi funding in Uganda.

Chapter 5: Zambia

Zambia

Gavi support for Zambia

Zambia first received Gavi support in 2001. Over the following 12 years, it has received a total of US\$93.2 million in Gavi funds for new vaccine introductions, Immunization Services Support (ISS), and Health system strengthening (HSS).

Table 63: Streams of Gavi support in Zambia

Gavi support	Period of Support	Total amount of funding (US\$)
Pneumococcal conjugate vaccine (PCV)	2012-2015	26,244,940
Rotavirus vaccine	2013-2015	7,571,997
Pentavalent vaccine*	2004, 2005-2015	63,544,363
Measles second dose (MSD)	2012-2014	615,018
Health system strengthening (HSS)	2007-2013	6,410,653
Immunization services support (ISS)	2001-2002, 2004, 2005	3,864,060
Injection safety support (INS)	2002-2004	689,237
IPV	2015-2017	1,856,000
Vaccine Introduction Grant	2001, 2012-2013, 2015	2,296,500

Source: <http://www.gavi.org/country/all-countries-commitments-and-disbursements>; accessed last April 21, 2015

*Earlier phase of support was for tetra DPT-hep B

Values shown represent Gavi commitments, those which Gavi intends to fund over the life span of the program, subject to performance and availability of funds.

Methods overview

Consistent with the prospective nature of the FCE, the evaluation reflected all Gavi supported activities, assessing implementation and related milestones by support stream. The table below provides an overview of the methods used, the sources of data, and the topics assessed by these methods.

Table 64: Evaluation methods, Zambia

Methods	Source consulted	Topics Investigated
Process Tracking	<ul style="list-style-type: none"> - Collected and reviewed documents including Gavi applications and decision letters, operational plans and budgets, Interagency Coordinating Committee (ICC) meeting minutes, the cMYP, and various reports that included the draft Post-Introduction Evaluation (PIE) report for PCV/rotavirus vaccine, Independent Review Committee (IRC) reports, internal appraisal report, and Annual Progress Reports (APR). - Conducted brief interviews with Ministry of Community 	<ul style="list-style-type: none"> - Information was collected based on relevant TOC milestones for PCV, HSS, rotavirus vaccine, and IPV, including: <ul style="list-style-type: none"> o Progress on cold-chain expansion and maintenance o Cold-chain capacity o Vaccine stock logistics o PCV surveillance o Post-introduction monitoring visits o PCV demand generation and awareness o Progress on HSS application

	<ul style="list-style-type: none"> - Development, Mother And Child Health (MCDMCH) and WHO stakeholders to confirm factual information - Observed Child Health Technical Working Group (TWG) meetings, Expanded Program on Immunization (EPI) TWG meetings, Interagency Coordinating Committee (ICC) meetings, HSS proposal inception workshop, post-training evaluation of rotavirus vaccine Training of Trainers (TOT), and the PCV/rotavirus vaccine Post-Introduction Evaluation (PIE) debriefing. 	<ul style="list-style-type: none"> o Coordination of HSS application process o Communication with Gavi SCM o IPV proposal development
Key informant interviews (KII)	<ul style="list-style-type: none"> - Conducted 32 country-level KIIs at the national- and subnational-levels, with stakeholders from the Ministry of Community Development, Mother and Child Health and partner organizations. - Conducted nine KIIs with global-level staff from the Gavi Secretariat and Alliance partners 	<ul style="list-style-type: none"> - Information was collected based on relevant TOC milestones for PCV, HSS, rotavirus vaccine, and IPV.
Health facilities survey (HFS)	<ul style="list-style-type: none"> - Stratified random sample of Zambian health facilities - The findings in this report represent a preliminary analysis; a more complete analysis will be included in subsequent reports 	<ul style="list-style-type: none"> - Routinization of newly introduced vaccines - Cold-chain capacity - Vaccine stock logistics - Vaccine surveillance - Post-introduction monitoring visits - Human resources capacity - Vaccine delivery
Analysis of administrative data on vaccine coverage	<ul style="list-style-type: none"> - Analyzed Health Management Information System (HMIS) data collected from health facility survey. 	<ul style="list-style-type: none"> - Routinization of newly introduced vaccines
Small area analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey data sources of household wealth and vaccination coverage 	<ul style="list-style-type: none"> - Estimation of district-level vaccine coverage and child mortality
Inequality analysis	<ul style="list-style-type: none"> - Compiled and analyzed all available survey data sources of household wealth and vaccination coverage 	<ul style="list-style-type: none"> - Estimation of vaccine coverage differences by wealth quintile and gender

Findings

As part of the Full Country Evaluation, we have compiled and systematically analyzed relevant data on key indicators at the national and, when possible, subnational level (Table 32 Table 33, and Table 34).

Table 32: Country characteristics of Zambia

Characteristic	
Demographic and economic indicators	
Total population (2013)	14,581,680
Birth cohort (2013)	624,919
GDP per capita (2014)*	US\$1,485
Health spending and Development Assistance for Health**	
Government health expenditure as source	US\$643 million
Development Assistance for Health, channeled through government	US\$592 million
Development Assistance for Health, channeled through non-government entities	US\$369 million
Total Development Assistance for Health	US\$4.28 billion

*GDP per capita source: IHME covariates database, reported in 2005 international dollars

** Health expenditure is explained in terms of government health expenditure as source (GHE-S), DAH channeled through government (DAH-G), and DAH channeled through non-government entities (DAH-NG). GHE-S + DAH-G gives the total government health expenditure, GHE-S + Total DAH gives total spending on health in the country. Health expenditure estimates 2011; Gavi disbursements 2001–2012.

Table 33: Vaccine coverage estimates, Zambia

Vaccine coverage	Most recent survey estimate*	WUENIC 2013 revision**	Self-Reported Coverage (WHO)***
DPT/Penta3 coverage	85.8%	79%	79%
DPT1-DPT3 dropout rate	10.0%	7%	7%
BCG coverage	94.9%	82%	82%
Polio3 coverage	77.6%	74%	74%
Measles coverage	84.9%	80%	80%
Percent fully vaccinated****	68.3%	N/A	N/A

* Most recent survey coverage estimates from 2013-2014 DHS

** WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) 2013¹³

***WHO vaccine-preventable diseases monitoring system, 2014 global summary¹⁴

**** BCG, measles and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth).

Table 34: Child, adult, and vaccine-preventable disease mortality in Zambia

Child, adult, and vaccine-preventable disease mortality	GBD2013*
All-cause mortality (risk per 1,000)	
Infant mortality (₁ q ₀)	50.9 (41.2, 62.9)
Under-5 mortality (₅ q ₀)	80.5 (63.4, 101.2)
Female adult mortality (₄₅ q ₁₅)	420.0 (387.4, 454.8)
Male adult mortality (₄₅ q ₁₅)	371.6 (340.1, 402.8)
Cause-specific mortality: children under 5 (rate per 100,000)	
Measles	6.6 (1.6, 18.5)
Diphtheria	0.07 (0.00-0.48)

Tetanus	1.8 (0.8-3.3)
Pertussis	4.2 (0.0-21.1)
Meningococcal infection	6.3 (3.3-10.5)
Diarrheal disease	183.4 (113.9-280.7)
Lower respiratory infections	263.3 (185.2-357.1)
Cause-specific mortality: all ages (rate per 100,000)	
Cervix uteri cancer	5.1 (3.6-6.9)
Acute hepatitis B	0.6 (0.4-0.8)
Cirrhosis of the liver secondary to hepatitis B	3.0 (1.9-4.3)
Liver cancer secondary to hepatitis B	0.7 (0.3-1.3)

* Mortality based on GBD2013 estimates

Analysis of immunization coverage, child mortality, and inequality

The FCE systematically compiled and analyzed all available data sources to estimate immunization coverage and child mortality by geography, household wealth, and gender. These estimates should be interpreted with caution. In some cases different surveys give disparate results, suggesting data quality issues. Additionally, not all data are identified at the lowest geographic level.

National-level estimates of vaccine coverage (Table 34) mask highly variable coverage rates among districts within Zambia, as shown in Figure 65 and Figure 66. DPT3 coverage increased in a majority of districts between 2000 and 2013, but there are large within-country inequalities in coverage in both periods. By 2013, DPT3 coverage exceeded 80% in approximately half of districts; at the same time, in around 10% of districts coverage was below 65%. Progress on increasing coverage of full vaccination (Bacillus Calmette–Guérin [BCG] vaccine, three doses of oral polio vaccine, three doses of DPT, and measles vaccine) was more mixed, with close to 40% of districts seeing increases between 2000 and 2013. Coverage of full vaccination was more variable than coverage of DPT3 in 2013, with a handful of districts below 20% and the best-performing district at 99%. District-level maps of coverage in 2000 and 2013 are available for all antigens (BCG, measles, three doses of DPT, three doses of pentavalent, and three doses of oral polio vaccine) in Annex 3.

Figure 65: District-level DPT3 coverage in Zambia, 2000 and 2013

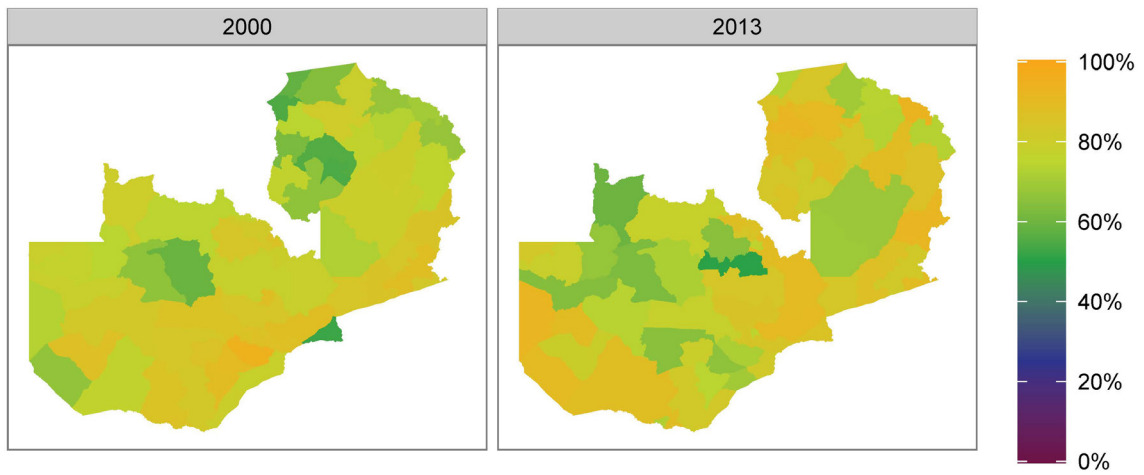
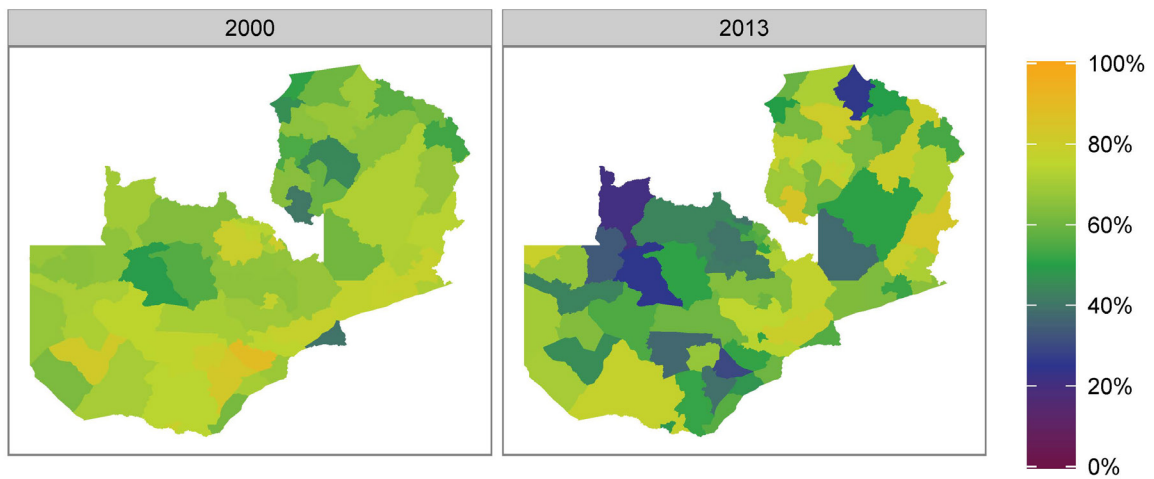


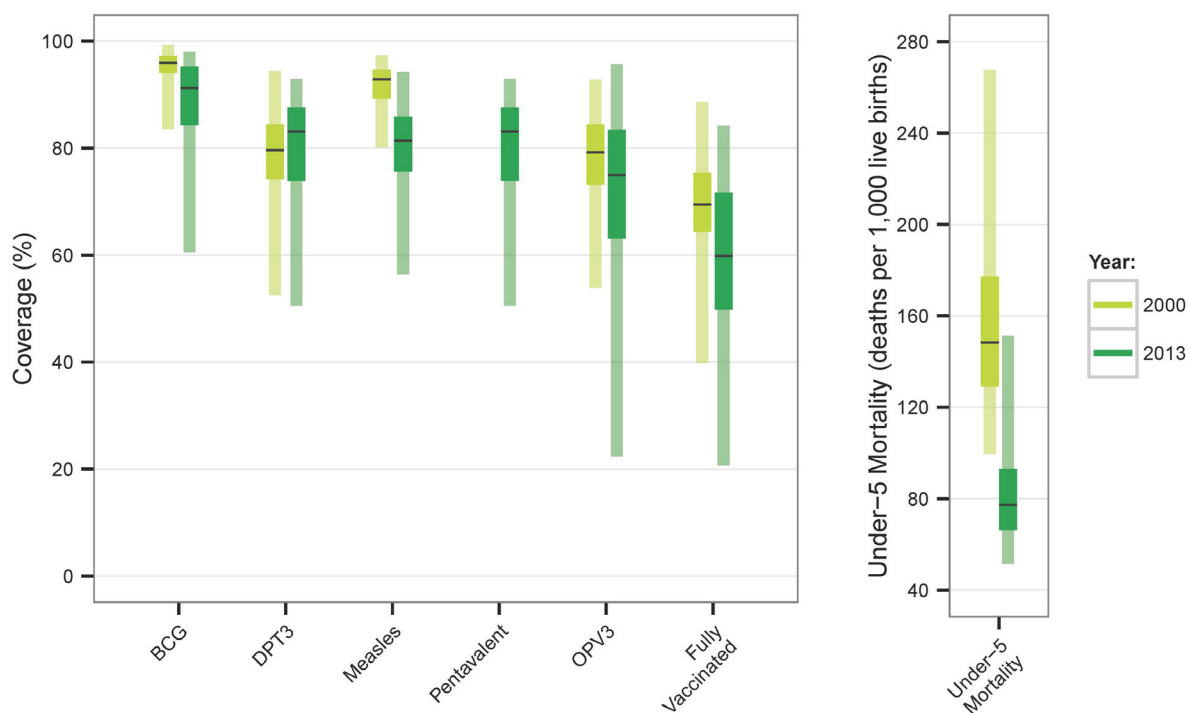
Figure 66: District-level fully vaccinated child coverage in Zambia, 2000 and 2013



The distribution of district-level vaccination coverage and under-5 mortality for 2000 and 2013 is visualized in Figure 67. Median coverage by antigen among districts has largely stayed the same or declined over this time period, particularly for full vaccination. At the same time, within-country inequalities, as measured by the range and interquartile range, have increased dramatically for most antigens.

Figure 67: Distribution of the district-level vaccine coverage and under-5 mortality in Zambia, 2000 and 2013

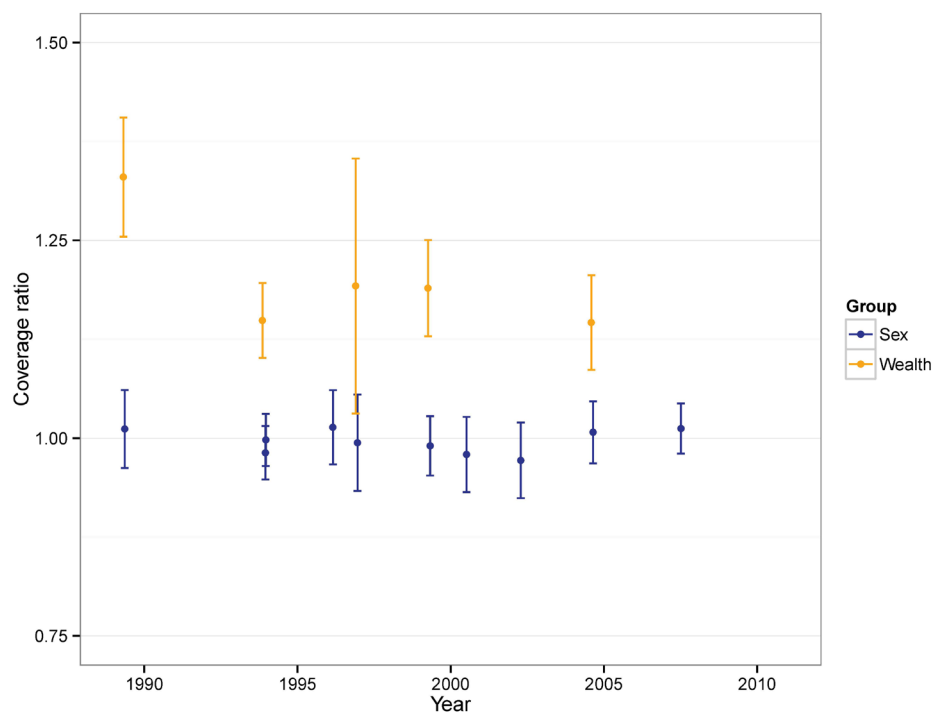
The horizontal line represents the median across districts. The thick vertical bar represents the interquartile range, while the thin vertical bar represents the range across districts.



In addition to within-country place-based inequalities, we also observe inequalities in vaccine coverage by household wealth in quintile to coverage in the poorest income quintile, this ratio is well above one (Figure 68). Although initial declines over the course of the early 1990s are apparent, there is little evidence of progress over the last two decades. In contrast, the ratio of coverage among male children to coverage among female children is indistinguishable from one in all periods.

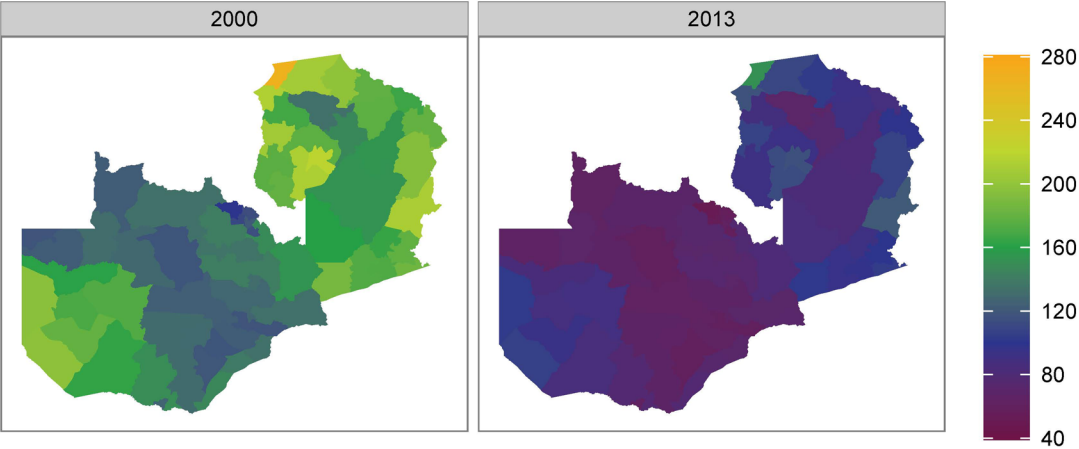
Figure 68: Coverage ratios of DPT3 vaccine by sex and wealth, Zambia

Wealth ratio is the ratio of DPT3 coverage in the richest quintile to coverage in the poorest quintile. Sex ratio is the ratio of DPT3 coverage in males versus females.



As is the case for vaccine coverage, national-level estimates of under-5 mortality (Table 34) hide large disparities in under-5 mortality among districts, as shown in Figure 69. In both 1990 and 2013, children in districts on the perimeter of the country, particularly in the north, northeast, and southwest, experienced noticeably higher risk of under-5 mortality than children in more centrally-located districts. Nonetheless, mortality declined in all districts over this period, leading to a decline in the median risk of under-5 death as well as a decline in between-district inequality, as measured by the range and the interquartile range in Figure 67.

Figure 69: District-level under-5 mortality, Zambia, 2000 and 2013



Overview of major immunization events

Figure 70: Timeline of major immunization events in Zambia *



*NVS for PCV was approved by Gavi on September 26, 2011. The proposal was submitted on June 11, 2011. NVS for Rotavirus vaccine was approved by Gavi on April 12, 2012; the application was submitted November 15, 2011. ISS support was approved by Gavi on April 21, 2009. HSS support was approved on August 1, 2007; the application was submitted in May 2007. EVMA occurred on July 2011.

Pneumococcal conjugate vaccine and measles second dose vaccine

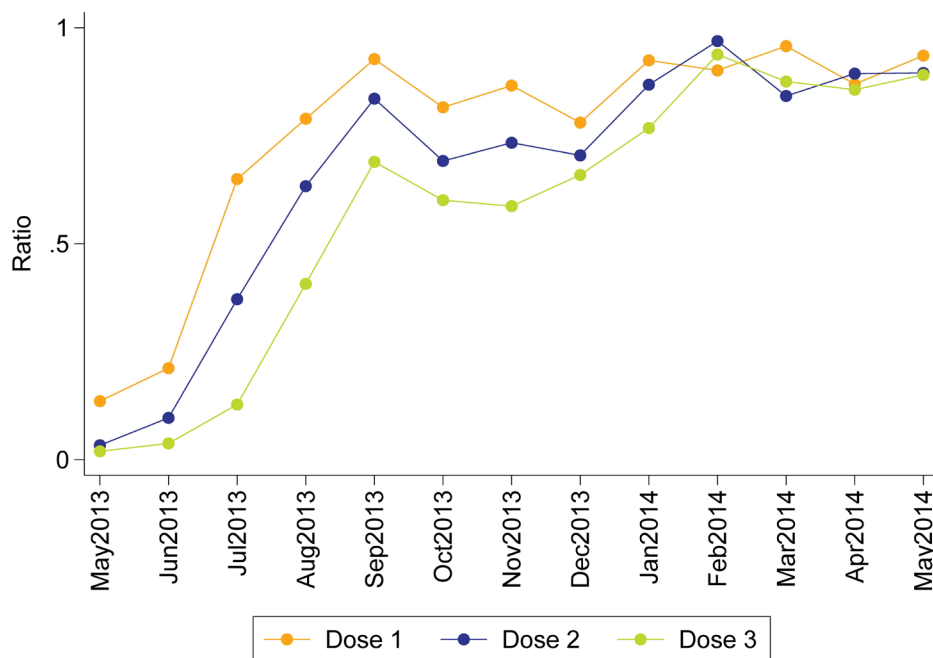
Pneumococcal conjugate vaccine (PCV) and measles second dose (MSD) were jointly launched in mid-2013; the related activities were captured in the 2013 Annual Report. In this report, we cover implementation related to the launch of PCV and MSD, as well as evaluation components like the health facility survey, which has facilitated follow-up on issues identified in the 2013 report.

In 2014, expansion of the cold-chain continued. Additional cooling equipment was installed in some districts with support from Japan International Cooperation Agency (JICA) through UNICEF and WHO. These have improved the delivery of PCV and other vaccines in these locales. In early 2014, the Child Health Unit (CHU) also launched a set of PCV and rotavirus vaccine post-introduction monitoring and supervisory visits to assess vaccine implementation progress in conveniently selected provinces and districts across Zambia. The visits occurred in late January 2014 over a two-week period. In July 2014, WHO and other partners (UNICEF, CDC) conducted a joint PCV, rotavirus vaccine, and MSD Post-Introduction Evaluation (PIE) as part of its routine vaccine introduction evaluation activities. The combined PIE was part of a comprehensive program review which also included disease surveillance review.⁴³ The findings and draft recommendations were shared in a debriefing meeting on August 1, 2014 with a range of country stakeholders.

At the time of the launch, the EPI program adapted the existing surveillance system to include pneumonia case reporting and investigation. Simultaneously, the Health Management Information System (HMIS) was adjusted to capture PCV coverage. Additionally, a reporting tool was developed and utilized for the reporting of adverse events following immunization (AEFI). In contrast to other countries where PCV was introduced, there was no parallel system implemented specifically for capturing PCV.

The Gavi FCE is in the process of compiling and analyzing the HMIS facility-level data, however, we also collected this data through the health facility survey (HFS). Figure 71 presents the ratio of PCV doses to the corresponding dose for pentavalent vaccine, based on data collected from HMIS through the health facility survey; this provides a measure of the extent to which PCV has been routinized in the immunization system relative to existing vaccines. The data show that, consistent with the findings from the 2013 report on PCV, a number of facilities launched PCV prior to the official launch in July (Figure 72). Of the number of facilities administering PCV increased most sharply at the month of the official launch, and the number of delivered doses increased steadily and plateaued around February 2014. At this point, the number of PCV doses delivered appears to be marginally lower than for pentavalent vaccine.

Figure 71: Ratio of PCV doses to pentavalent vaccine doses in Zambia, May 2013 to May 2014



Summary of progress

Table 35 presents a summary of the progress, successes, challenges, and responses, related to the routinization of PCV during this evaluation period. PCV and rotavirus vaccine activities have experienced a number of common successes and challenges; therefore we jointly discuss the findings around PCV and rotavirus vaccine in the following section.

Table 35: Summary of country progress

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Timely and adequate planning	
- Zambia first intended to introduce PCV in April 2012. However, CHU made the recommendation that PCV and MSD be launched simultaneously.	- There were multiple postponements of the launch date caused by delays in the receipt of VIG and by subnational disbursement.
Sufficient funding is available on time	
- The majority of activities undertaken in preparation for the launch were funded by the Gavi Vaccine Introduction Grant (VIG) and government funds. Other donors provided funding for discrete activities such as cold-chain improvement, social mobilization, and demand generation.	- The process surrounding the transfer of funds, from Gavi and from government, was characterized by delays and uncertainty. These stemmed from the delayed arrival of the VIG, the delayed release of funds from UNICEF to provinces/districts (once the VIG had arrived in country) and a lack of communication between the national and subnational levels about the disbursement of funds.
Adequately skilled health workers available	

<ul style="list-style-type: none"> - Training was cascaded from the national-level Training of Trainers (TOT) to the districts and health facilities. - Because of the revised Daily Sustenance Allowance (DSA) available funding was insufficient. Stop-gap funds were requested from and provided by GlaxoSmithKline (GSK). 	<ul style="list-style-type: none"> - Initially, trainings were delayed by a lack of funding. District-level informants also noted that the funds they received for training were inadequate to conduct the required level and quality of training. It was not explained to the district why the budget for training was cut. - There was a lack of adequately trained health workers. Not all health facilities have conducted a PCV-related training in the past twelve months, with 26.4% of health facilities reporting no staff having ever received a training for PCV vaccine during the last twelve months (<i>see Annex 13 for detailed results of HFS</i>).
Cold-chain logistics system improved	
<ul style="list-style-type: none"> - The government of Zambia, with assistance from country partners, installed five additional 40 m³ cold rooms at the national level and five 30 m³ cold rooms at the provincial level, satisfying the Gavi condition for cold-chain expansion (<i>2013 Annual Report</i>). 	<ul style="list-style-type: none"> - Suboptimal availability of vaccine stickers on vaccine storage equipment. About 30% of facilities have vaccine storage equipment without sticker (<i>HFS</i>). - Many facilities face persistent cold-chain issues. Of the 140 facilities who reported on availability of electricity, 10 facilities reported 12 or more hours of no electricity per typical day (<i>HFS</i>). Some program managers and health workers over-estimated the capacity of cold-chain to maintain internal temperature during electrical outages (<i>KII</i>). Additionally, facilities operating on a non-electrical energy source still had problems maintaining cold-chain due to erratic supply of the energy source, specifically for those operating on gas and kerosene (Figure 74 and Figure 75) (<i>KII, HFS</i>). - Intermittent breakdowns in cold-chain equipment in some provinces or districts have been reported (<i>KII</i>) and verified during the HFS. In addition, temperature of vaccine storage equipment was found to have been out of range in 30% of observation time during HFS (Figure 84, Figure 85).
PCV readiness confirmed	
<ul style="list-style-type: none"> - PCV10 arrived in country in October 2012, well before the trainings were implemented. 	<ul style="list-style-type: none"> - Our interviews and observations suggest that PCV10 readiness was never specifically considered or discussed. Though the readiness requirements were not met, the vaccine shipment was received regardless.
Sufficient volume of quality vaccines available	
<ul style="list-style-type: none"> - PCV arrived in Zambia in October 2012. PCV was kept in the national store until early 2013 and a decision was made to distribute the vaccines after the trainings had been conducted. 	<ul style="list-style-type: none"> - There have been PCV stock-outs in some facilities. This has been attributed to the discrepancy between official figures from Central Statistical

	<p>Office (CSO) and head count conducted by facilities; the official statistics tend to understate the actual vaccine demand (KII). In particular, PCV stock outs were reported in 10 of the 22 districts and across all platforms of health facilities. Five to ten percent of health centers and health posts experienced continuous stock out of four weeks (Figure 74).</p> <ul style="list-style-type: none"> - There was a lack of motorized transport-means hinders vaccine pick-up in a number of facilities. Among the HFS surveyed facilities, 28% did not have access to a motorized vehicle for vaccine pick-up (HFS). - There was a lack of trained EPI logisticians at the district level (KII).
Updated monitoring tools available	
<ul style="list-style-type: none"> - Monitoring tools, including updated under-five cards and vaccine registers, were created in advance of the launch. 	<ul style="list-style-type: none"> - Stocks of the updated tools were reported in planning meetings to be insufficient and many facilities were reported to be using old registers without space for the new vaccines. - Official immunization cards, official child registers, official vaccine and injection control books, official AEFIs forms, and official VPD field guides were absent in a large proportion of facilities, with immunization cards being the most available (Figure 89). - Inadequate supply of the under-five cards led to private sale of the cards. - For adverse events following immunization (AEFI), most facilities do not report these due to lack of forms (KII, HFS).
Adequate demand for PCV generated	
<ul style="list-style-type: none"> - Social mobilization was highlighted as an area of success for PCV. - Social Mobilization Committee members expressed concerns about combining media spots for PCV and MSD, cautioning the public may not be able to differentiate between the two separate vaccines being introduced. This concern was presented to the Child Health Technical Working Group who decided that the spots should be differentiated. - Initially, only one brochure was available per facility. Church of Latter Day Saints offered to print and distribute 100,000 additional brochures. 	<ul style="list-style-type: none"> - The social mobilization activities had to be continually rescheduled as the national PCV launch date was repeatedly postponed.
Successful launch of PCV10	
<ul style="list-style-type: none"> - The July 9 launch of PCV was a successful event. 	<ul style="list-style-type: none"> - A number of districts launched PCV before the national launch due to inadequate communication

	between national and subnational levels about postponements (Figure 72).
Routinization	
<ul style="list-style-type: none"> - Most health facilities had rolled out PCV by January 2014, within six months from official launch date (Figure 72), though a number of facilities introduced the vaccine prior to launch date (<i>HFS</i>). - PCV doses are now delivered through the routine EPI program. (<i>KII, HFS, HMIS</i>). - Joint PCV and rotavirus vaccine PIE were conducted within the stipulated 12-month period. - The addition of PCV and rotavirus vaccines is perceived as having strengthened, rather than compromised, the routine EPI delivery by improving logistics, capacity building, acceptance of vaccines by the community, and by generating a high demand for vaccines in general. Vaccine introduction was used as an opportunity to strengthen other health issues such as diarrhea control in case of rotavirus vaccine (<i>PIE, MO</i>). 	<ul style="list-style-type: none"> - The human resource crisis remains a challenge on EPI, especially in rural areas. Health facilities are struggling to conduct outreach immunization services, which affects PCV coverage rate (<i>KII</i>). - Inability to determine level of coverage of PCV due to weaknesses in HMIS (e.g., discrepancies between CSO official population figures and head-count/actual population in some districts). Some districts recorded more doses of PCV2 than PCV1 and more doses of PCV3 than PCV2 (<i>KII</i>). - Data on PCV doses are missing for a different number of months through HMIS across all platforms (<i>HFS</i>) (Figure 87). - A dropout rate of 31% was observed across districts and platforms of health facilities between PCV1 and PCV3 (<i>HFS</i>)(Figure 74)¹⁰

¹⁰ Health facilities in Zambia are divided into four categories: hospitals, hospital-affiliated health centers (HAHC), health centers, and health posts. Hospitals are divided into three levels and are intended to serve a catchment population larger than 80,000. A hospital-affiliated health center is a smaller health unit located within the hospital's vicinity and are similar to health centers. Health centers are intended to serve as primary care centers, with urban health centers serving catchment populations between 30,000 and 50,000 and rural health centers serving catchment areas of approximately 10,000 people or a radius of 29 kilometers. Health posts are intended to operate as basic health centers for sparsely populated areas, with rural health posts serving populations of approximately 3,500 people (500 households) and urban health posts serving populations of approximately 7,000 people (1,000 households). The types of health services offered at health posts are basic first aid rather than curative. ⁴⁴

Figure 72: Date of first PCV vaccination in facilities compared to official PCV launch date in July, 2013

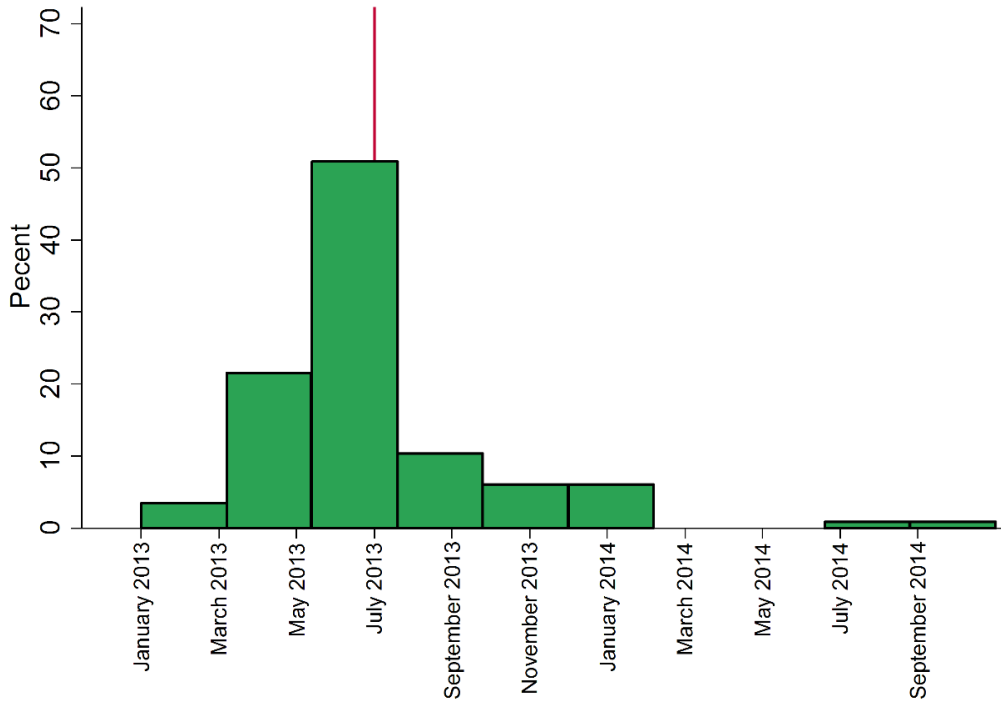


Figure 73: Drop out between first and third dose of PCV by platform of health facilities, June 2013 to May 2014*

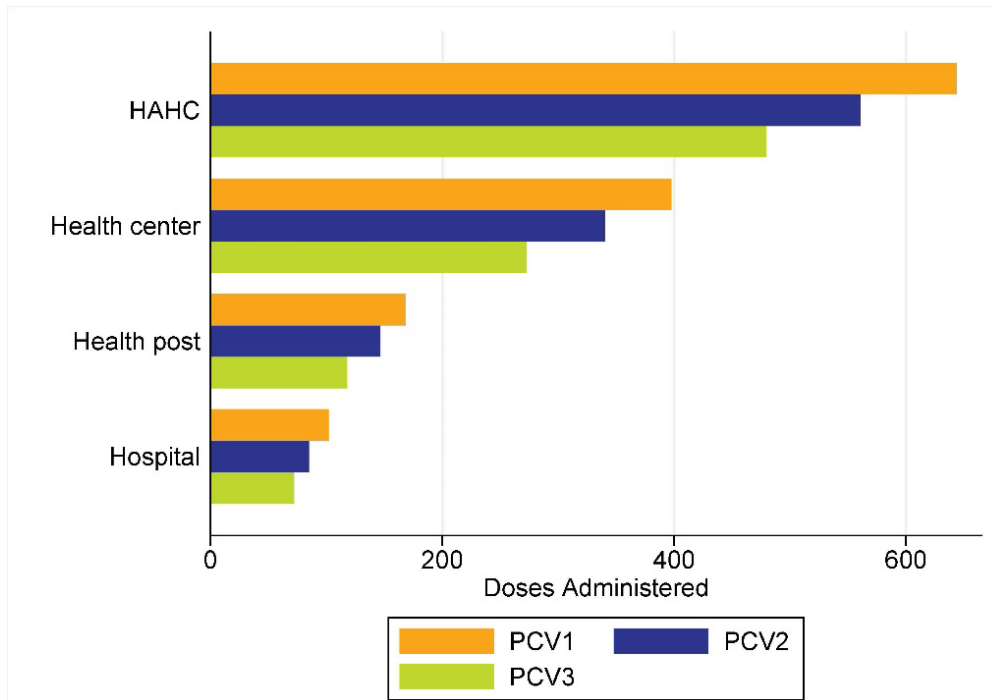
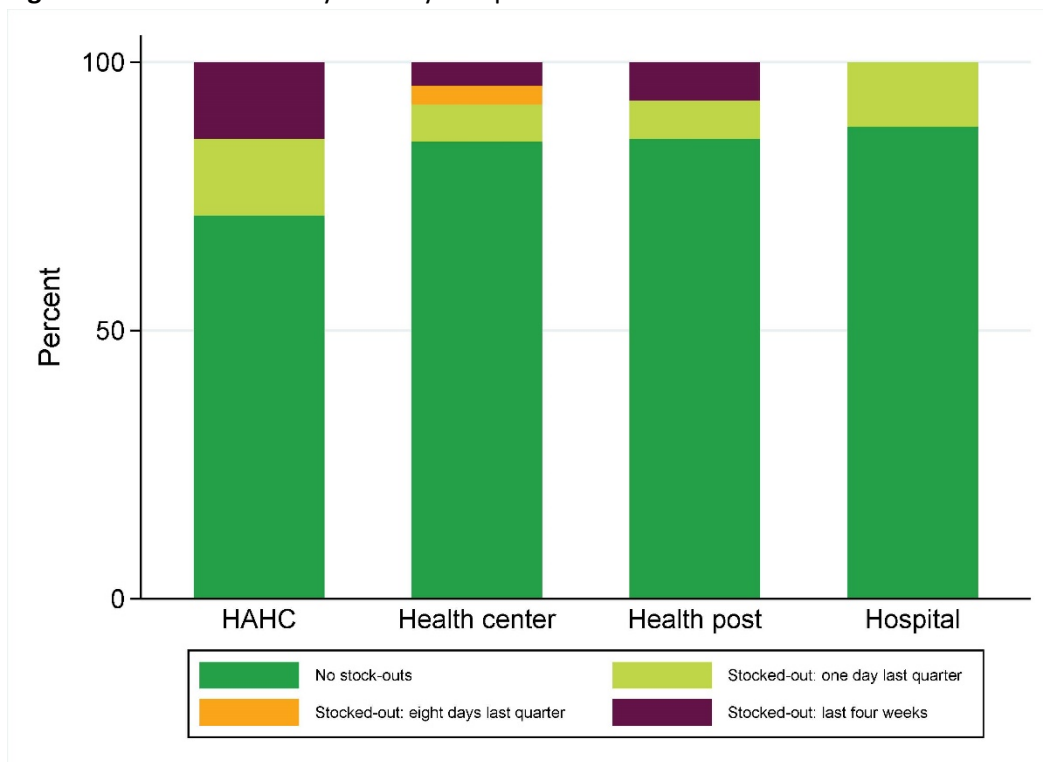


Figure 74: PCV stock-out by severity and platform of health facilities*



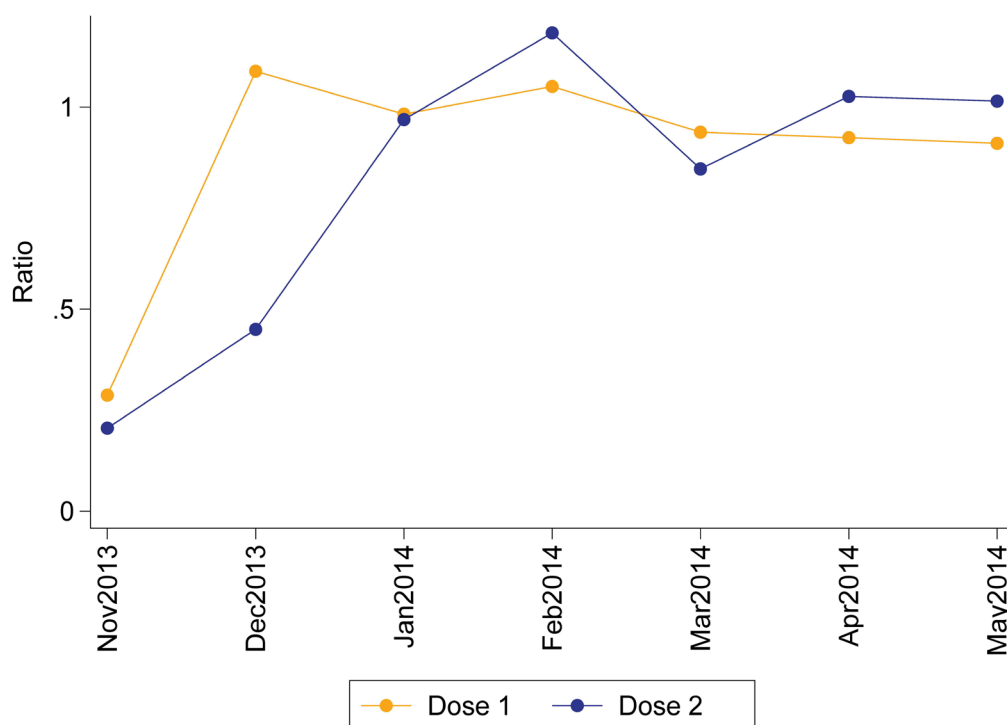
*HAHC is a hospital affiliated health center, see footnote in Table 109 for description of health facility types.

Rotavirus vaccine

Two-dose rotavirus vaccine (Rotarix) was launched in Zambia in November 2013, about four months after the simultaneous launch of PCV and MSD. Prior to the national rollout, a pilot was conducted from January 2012 into 2013, led by the Centre for Infectious Disease Research in Zambia (CIDRZ) in three districts of Lusaka province. The pilot study was used to inform the subsequent national introduction of rotavirus vaccine. As noted in the PCV section, post-introduction monitoring and supervisory visits and a PIE were conducted jointly for PCV in 2014.

Rotavirus vaccine delivery appears to have been scaled up over a shorter time period than for PCV (Figure 75) and was at similar levels to that pentavalent vaccine one to two months following the introduction month. This suggests that the introduction and routinization of rotavirus vaccine was smoother than PCV. As we discuss in the later sections, the roll out of rotavirus vaccine has benefited from lessons learned through PCV implementation and a rotavirus vaccine pilot.

Figure 75: Ratio of rotavirus vaccine doses to pentavalent vaccine doses in Zambia, May 2013 to May 2014



Summary of progress

Table 36 presents a summary of the progress and successes as well as challenges and responses related to the introduction of rotavirus vaccine in Zambia.

Table 36: Progress of implementing rotavirus vaccination with selected key challenges and successes

Milestone heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Timely and adequate plan and budget for rotavirus vaccine national introduction	
<ul style="list-style-type: none"> - The rotavirus vaccine introduction plan and budget were developed (<i>KII/document review</i>). 	<ul style="list-style-type: none"> - The final plan and budget for rotavirus vaccine introduction were scaled-down because the program could not secure sufficient funding commitments from government and partners (<i>KII</i>). - Skills in costing as an input into planning and budgeting process were inadequate and need more support (<i>KII</i>).
Valuable technical assistance provided	
<ul style="list-style-type: none"> - EPI partners provided technical assistance (TA) during the vaccine introduction. Some lessons learned during rotavirus vaccine pilot were applied during national introduction (<i>KII</i>). 	<ul style="list-style-type: none"> - Competing priorities and busy schedules from some country level partners meant they were not always available to provide TA. However, much of the TA required for the rotavirus vaccine introduction was gathered through the experience of the pilot (<i>KII</i>).
Sufficient funding available in time	
<ul style="list-style-type: none"> - Country level partners such as GSK and Centre for Infectious Disease Research in Zambia (CIDRZ) supplemented the budget (<i>KII</i>). 	<ul style="list-style-type: none"> - Funding was inadequate for some components of the introduction, such as training and social mobilization. The budget was inadequate largely due to increase in allowances for civil servants (<i>KII</i>).
Cold-chain and logistic system is prepared for rotavirus vaccine	
<ul style="list-style-type: none"> - The cold-chain was expanded country-wide with support from JICA through UNICEF and CIDRZ for PCV introduction which later benefited the Rotavirus vaccine introduction. Cold-chain expansion is ongoing with support from country level partners such as CIDRZ and JICA. The government has also provided funds for cold-chain expansion (<i>document review, KII</i>). 	<ul style="list-style-type: none"> - Facilities with no access to electricity still have problems maintaining cold-chain due to erratic supply of the other energy sources (paraffin/gas) (<i>KII, FCI</i>). - Intermittent breakdowns in cold-chain equipment in some provinces or districts (<i>meeting observation, KII, HFS</i>). - Cold-chain problems have been cited as contributing to vaccine stock-outs in the country (<i>KII, HFS</i>).
Sufficient volume of quality rotavirus vaccine available	

<ul style="list-style-type: none"> - While there was a global deficit of the rotavirus vaccine, Zambia was prioritized to receive vaccine supply in order to avoid a gap in supply between the ending of the pilot program and the beginning of the national introduction (<i>KII</i>). 	
<p>Adequately skilled health workers are available</p>	
<ul style="list-style-type: none"> - Learning from PCV launch, a national-level EPI logistician was recruited with support from CIDRZ ahead of rotavirus vaccine introduction. After the rotavirus vaccine launch, the government also recruited a national-level EPI logistician to fill a vacancy in the establishment. The two are responsible for vaccine logistics management which previously was managed by staff not qualified in that position (<i>meeting observations, KII</i>). 	<ul style="list-style-type: none"> - Post-training evaluation of the participants at the TOT using WHO guidelines by Child Health Unit (CHU) and other stakeholder who were facilitating at the training indicated unsatisfactory performance by participants from 11 districts (<i>meeting observations</i>). <p>Initial discussions indicated that there was a need to provide supportive training in those districts. However, there was no confirmed funding and time was limited before the launch date. At the time of the HFS, 30.0% of surveyed facilities had never received any rotavirus vaccine-related training during the last 12 months (<i>HFS</i>).</p> <ul style="list-style-type: none"> - PIE noted inadequacies in human resources at facility levels, especially in rural areas. A slight difference was observed in the ratios of full-time equivalent staff conducting vaccination sessions per 100 less than one-year catchment children: 2.0 for rural areas vs 2.4 for urban areas (<i>meeting observations, HFS</i>).
<p>Rotavirus vaccine monitoring systems are available</p>	
<ul style="list-style-type: none"> - Additional funding and technical support were provided to the vaccine surveillance site at University Teaching Hospital to monitor the rotavirus vaccine (<i>KII</i>). - An additional surveillance site was also established at a children's hospital, Arthur Davidson Hospital, in Ndola (<i>KII</i>). - Rotavirus vaccine was included in child immunization cards ahead of the launch and in the HMIS system (<i>document review, KII, HFS, HMIS data</i>). 	<ul style="list-style-type: none"> - Based on HFS, a number of facilities reported not having adequate monitoring tools (e.g., AEFI forms, child immunization cards, vaccine stock cards) (Figure 89) (<i>HFS</i>). - Weaknesses of the HMIS in capturing vaccine delivery persist (Figure 87 and Figure 88) (<i>HFS</i>).
<p>Adequate demand for rotavirus vaccine generated</p>	

<ul style="list-style-type: none"> - Social mobilization activities were conducted countrywide through mass media, traditional institutions and also during routine antenatal and growth monitoring visits (<i>meeting observation, KII</i>). 	<ul style="list-style-type: none"> - Funding was inadequate for this component, which led to reduction in number of social mobilization activities and information, education and communication (IEC) materials (<i>meeting observation, KII</i>). - Mothers raised concern that “too many” vaccines were introduced (<i>KII</i>).
<p>Timely access to accurate information on implementation status</p>	
<ul style="list-style-type: none"> - All planning meetings were attended by country partners. Stakeholders had access to information through TWG meetings (<i>meeting observation</i>). 	<ul style="list-style-type: none"> - Feedback mechanism from surveillance site and HMIS unit into child health TWG is still weak. This weakens the ability to know implementation status and to adjust plans where necessary.
<p>Timely and appropriate adjustments according to information</p>	
<ul style="list-style-type: none"> - Setting of launch date was delayed until funds were secured. Date was set by stakeholders when funds were secured. This was an adjustment based on PCV experience (<i>meeting observation</i>). 	
<p>Successful national launch of rotavirus vaccine</p>	
<ul style="list-style-type: none"> - The rotavirus vaccine was launched nationwide as scheduled in November 2013 (Figure 76) (<i>meeting observation</i>). 	
<p>Successful routinization of rotavirus vaccine</p>	
<ul style="list-style-type: none"> - Rotavirus vaccine doses are captured in HMIS (<i>document review, FCI, HFS, HMIS data</i>). - PIE conducted in July 2014 led by WHO with two external consultants. Preliminary findings noted that cold-chain was generally deemed adequate though with little capacity for buffer stocks (<i>meeting observation, FCI, KII</i>). 	<ul style="list-style-type: none"> - There have been stock-outs of rotavirus vaccine in some districts and facilities (FCI, KII, HFS) (Figure 77) - In the first year of implementation, rotavirus vaccine coverage was forecast to be 85% in 70% of districts, which is 60% national coverage; the program planned to start slow and build up. - Dropout rate for rotavirus vaccine between the first and second dose was 29% (Figure 78) (<i>HFS</i>). - Social mobilization for routinization is weak as most of the social mobilization occurs during launches and specific campaigns (<i>KII</i>).

Figure 76: Date of first rotavirus vaccination compared to official rotavirus vaccine launch date (red line)

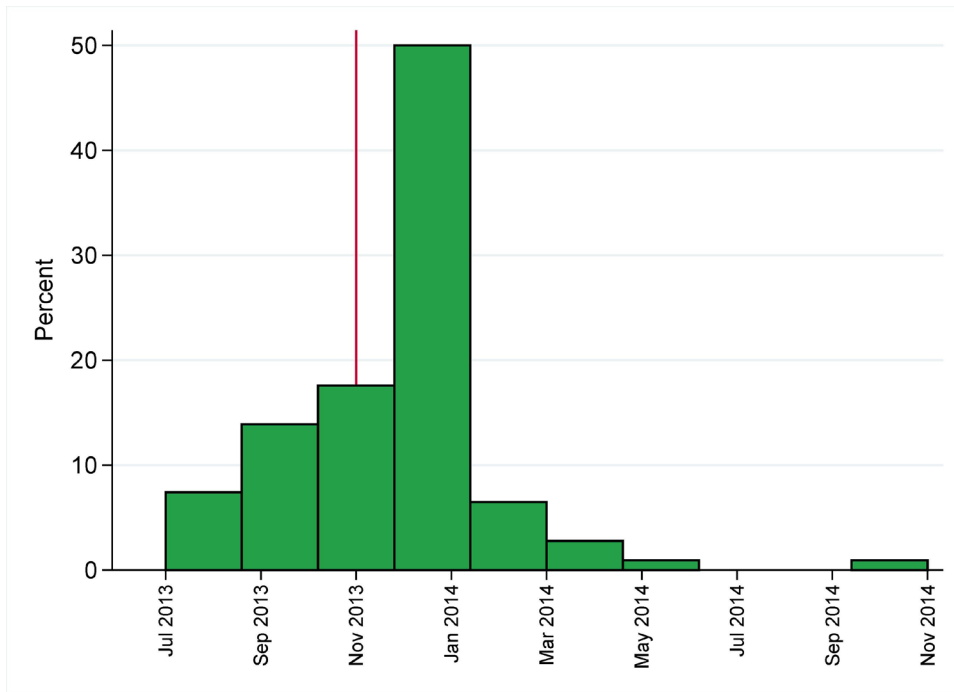
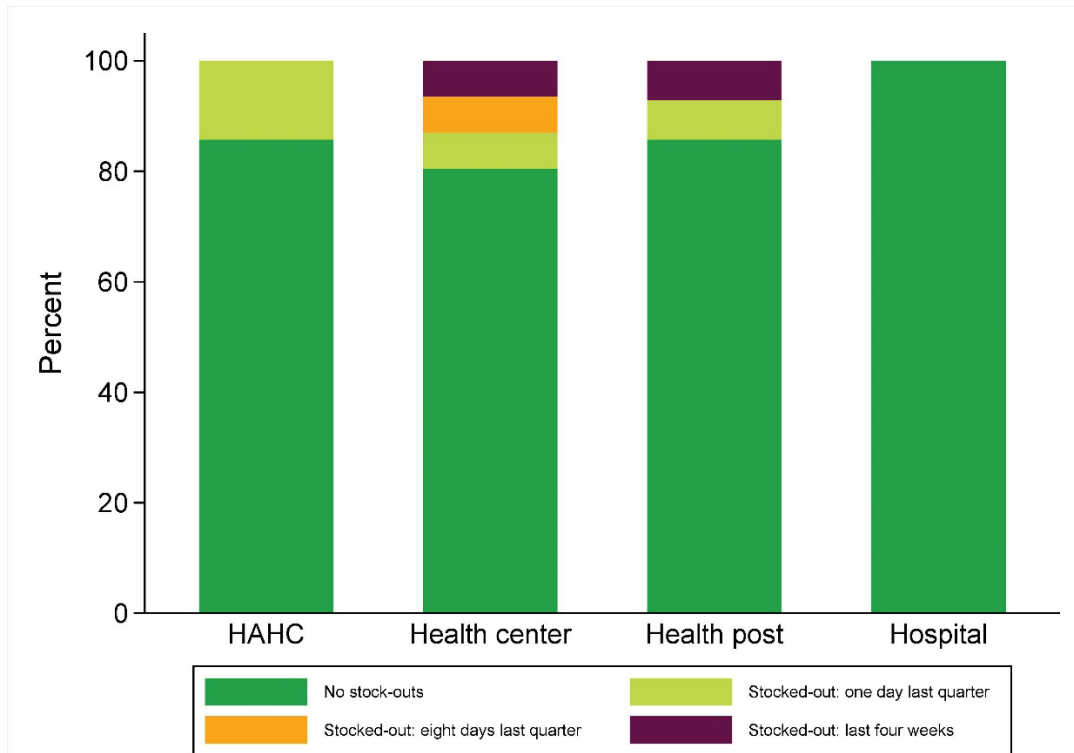
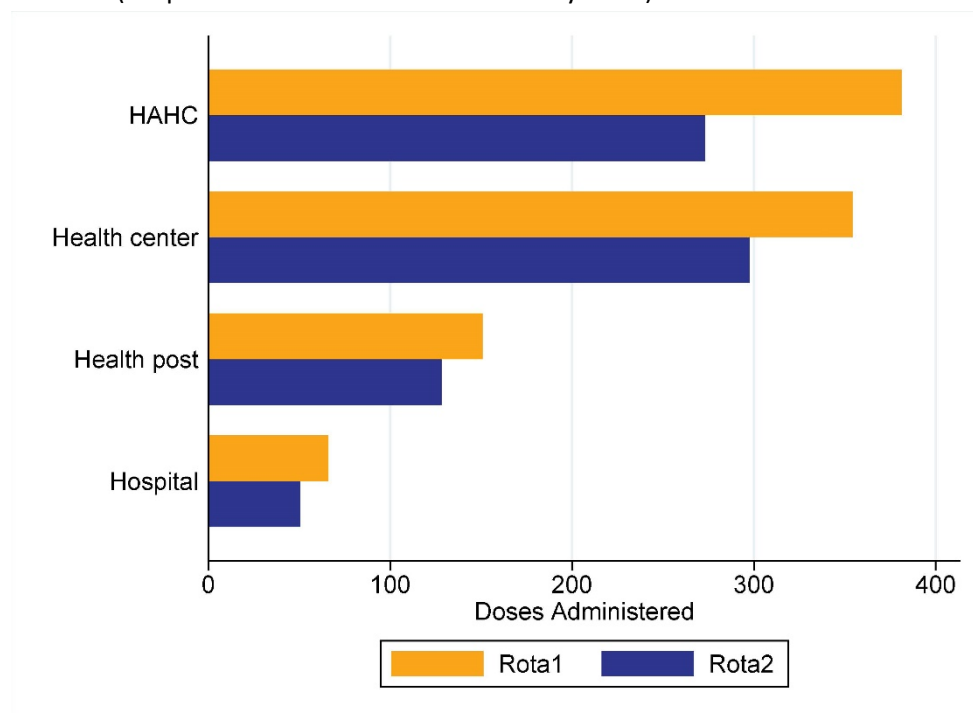


Figure 77: Rotavirus vaccine stock-out by severity and platform of health facilities*



*HAHC is a hospital affiliated health center, see footnote in Table 109 for description of health facility types.

Figure 78: Drop out of rotavirus vaccine doses between first and second dose by platform of health facilities (drop out between June 2013 and May 2014)



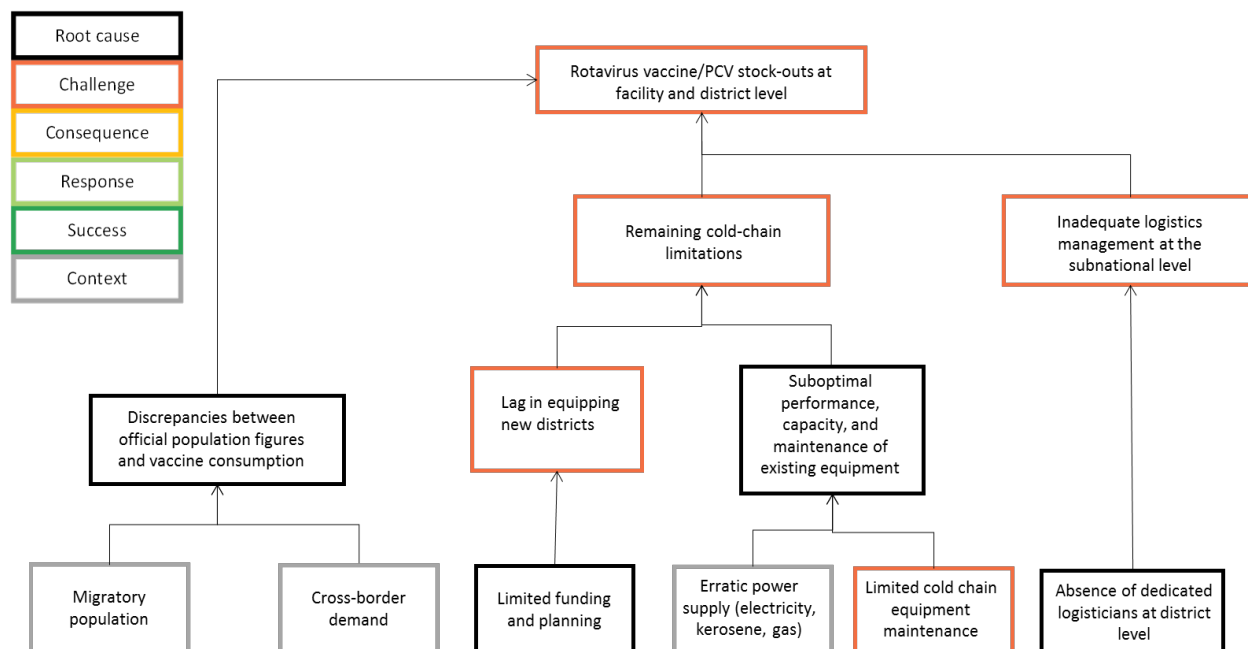
Analyses of major challenges & successes

The Gavi FCE identified three major findings from the analysis of Zambia's introduction of PCV/MSD and rotavirus vaccine.

Finding 1

Discrepancies between vaccine consumption and official target population figures that are used to determine vaccine supply, remaining cold-chain inadequacies at facilities, and lack of adequate planning and vaccine stock management at the subnational level contributed to stock-outs of both PCV and rotavirus vaccines.

The first major challenge affecting both PCV and rotavirus vaccine is vaccine stock-outs (Figure 74 and Figure 77). We identified a number of root causes of stock-outs in Zambia as summarized in Figure 79.

Figure 79: Root cause analysis of PCV and rotavirus vaccine stock-outs

The first underlying cause of stock-outs of PCV and rotavirus vaccine are discrepancies between vaccine consumption and the official population figures. The decision about the quantity of vaccines to disburse to districts, and subsequently to facilities, is based on official figures provided by the government of Zambia. That is, districts will receive vaccines based on the official census of their population, a proxy for vaccine demand for each district. This trickles down to facilities, which receive their vaccines from district offices. Any deviation from this protocol must be justified. However, the perception from key informants is that justifying such deviations is complex. Most districts and facilities claimed that the Central Statistics Office (CSO) underestimated their target populations and therefore the demand for vaccines. For example, the official numbers provided by the CSO are less than the headcounts conducted with the help of community health workers at the facility level. Due to these discrepancies, facilities ended up receiving less vaccine stock than needed.

In addition to inaccuracies in target population estimates, two additional factors contributed to discrepancies between population figures and vaccine consumption. Firstly, some districts experience seasonal migration, causing seasonal variations in vaccine demand. For example, many fishing populations set camps along fishing waters during fishing seasons. Due to seasonal bans on fishing and flooding of some river bank areas, these populations are forced to temporarily migrate to other areas for other economic activities. This has a pronounced impact on districts and facilities servicing fishing populations.

Secondly, districts located along the international borders experience increased vaccine demand from neighboring populations. With laxity in border control in some areas and weak EPIs in some neighboring countries, districts along the borders have noted increases in EPI demand as a result of foreigners

crossing into the country to access immunization and other health services. This has contributed to the discrepancy between the official population counts and actual demand at the district and facility levels.

Most mothers utilize our facility being a border town. We have people bringing their children from across the border and this affects our figures greatly. PCV is out of stock, rotavirus vaccine stocks are available. (Subnational KII)

Both government and stakeholders are cognizant of these problems and these findings are consistent with the findings from the PIE which noted that:

[The Central Statistical Office] frequently underestimates target populations ... which health worker are officially required to use for requisition of vaccines and supplies leading to supply stock-outs. [In addition], Zambia's landlocked positions exposes her to regional cross border human traffic with increased populations at catchment population in border communities ... threatening coverage levels.

Though appealing, head counts have limitations. They cannot be replicated at the national level and are prone to double counting, which may produce inflated figures. Some districts and facilities resort to using average monthly vaccine consumption to forecast vaccine demand. For instance, one key informant stated:

... Our head count is more than the CSO figure. The EHT and our Community Health Workers do the headcount. We order for new stocks using our Average Monthly Consumption. (Subnational KII)

The government looked into this issue and is exploring other options like utilizing the birth registry and projects such as Better Immunization Data (BID) in order to come up with more reliable data. Although in preliminary stages, there are also plans to pilot a central immunization registry in the southern province.

A second underlying cause of vaccine stock-outs are remaining cold-chain inadequacies. During the PCV introduction and rotavirus vaccine pilot, the cold-chain was expanded at all levels: national, provincial, district, and facility level.

Despite investments in cold-chain expansion linked to the introductions, vaccine storage equipment is still limited in many health facilities and the maintenance-required logistics and human resources are also scarce. The findings from the health facility survey confirm these cold-chain inadequacies (Figure 82). These deficiencies contribute to stock-outs because facilities are unable to hold a sufficient amount of vaccine and/or adequate buffer stocks. These limitations were noted in the PIE. Some health facilities were noted to have obtained vaccine stocks twice a month rather than once a month to accommodate having inadequate space to store them, leading to some transport challenges. For instance, a government key informant noted:

All challenges which Lusaka facilities faced were being faced by other facilities. E.g. Kafue/Chilanga had big challenges with space. We used a push method initially, but with such

areas resorted to using a pull method, and had extra visits to collect more vaccine as it ran out. This was applied to other sites during roll out, although this increased transport and other costs.

Cold-chain inadequacies also stem from delays in equipping recently formed districts. Since 2012, the government of Zambia has embarked on the creation of new districts for administrative purposes. As a result of these administrative changes, these new districts require their own cold-chain equipment and logistics arrangements.

As part of the national cold-chain expansion strategy, the government introduced a specific budget line dedicated to cold-chain equipment procurement. In addition, country partners such as JICA and CIDRZ have contributed to solutions by procuring more fridges and training more cold-chain personnel in maintenance of cold-chain equipment. For instance, JICA provided a grant of about ZMK\$10 million to support the expansion of cold-chain in October 2014 through procurement of new fridges for districts or facilities that lacked fridges or needed replacements for broken fridges. CIDRZ is projected to spend US\$2 million towards this cold-chain expansion. This effort is aimed at improving the country's vaccine management through infrastructure support. In addition, the government is shifting from kerosene and gas fridges to solar fridges only in these current procurements.

Cold-chain inadequacies are also reflective of suboptimal maintenance of existing equipment, in terms of both the availability of power to operate cold-chain equipment and continued maintenance of cold-chains. Results from the HFS show extent of problems of maintaining cold-chain temperatures (Figure 82 and Figure 83). Facility personnel are notified if out-of-range temperatures are noted as part of the survey. In addition to electricity outages, it is a larger challenge to maintain sufficient fuel for kerosene and gas fridges. While the number of facilities operating on power from energy sources different from electricity in HFS is small, they still are indicative of the situation given the convergence of the information from HFS and what has been noted from the KII. Many kerosene fridges may go without fuel and associated supplies such as wicks and gas for prolonged periods. This led to cold-chain breakdown that resulted in stock-outs. Health facilities usually depend on neighboring facilities with functioning cold-chains in such situations, but sometimes there are transportation challenges due to long distances. As a result, some facilities have gone for months without immunization activities because there are no vaccines. They fail to request for vaccine stocks solely because they lack the needed cold-chain to store the vaccines. One key informant stated:

The only challenge we have is we have run out of the commodity [and] are currently stocked-out. Our fridges run on gas and have not had gas since August [two months ago]. The district office is slow to respond [and] and we are currently stocking our vaccines at [another health facility 10 km away] because they have electricity fridges there. (Subnational KII)

Figure 80: Examples of vaccine storage equipment temperature recorded from facility charts and temperature logger in facilities running on different types of energy sources

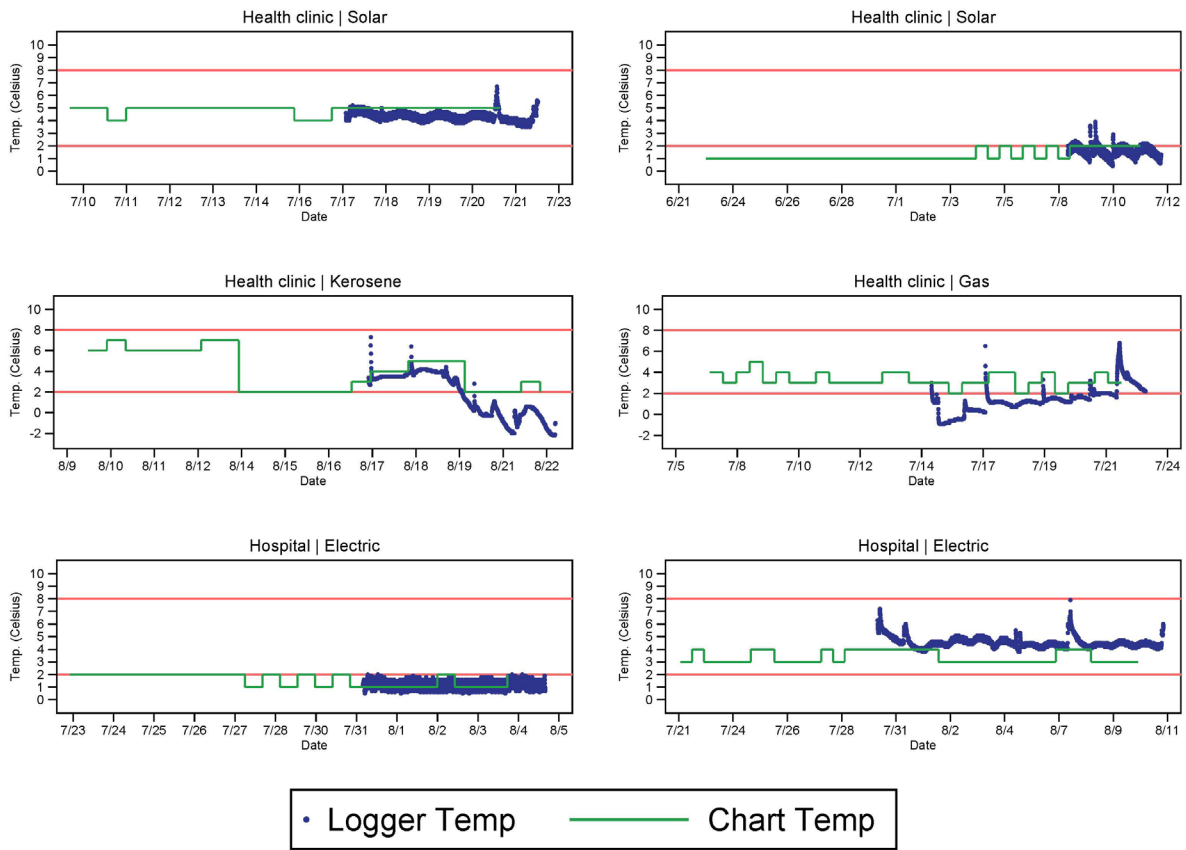


Figure 81: Mean percent time vaccine storage equipment in and out of range by type of operating energy source, temperature logger data

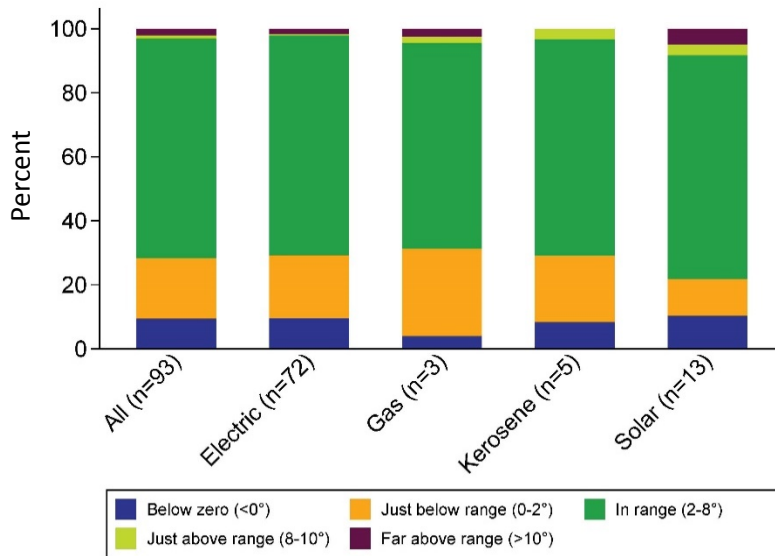


Figure 82: Mean percent time vaccine storage equipment in or out of range by platform of health facilities, temperature logger data*

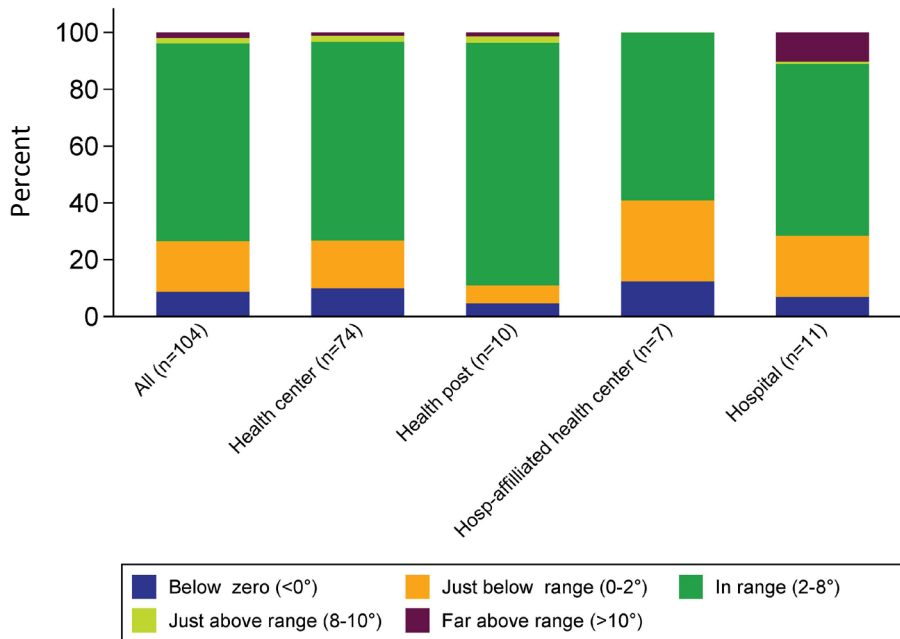
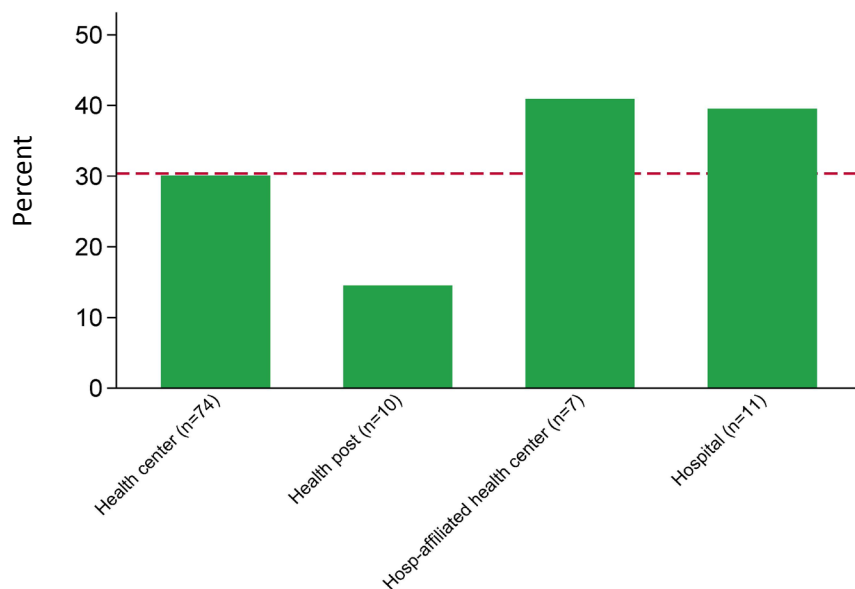


Figure 83: Mean percent time vaccine storage equipment temperature out of range (less than 2°C or greater than 8°C) by platform of health facilities, temperature logger data*



*HAHC is a hospital affiliated health center, see footnote in Table 109 for description of health facility types.

In terms of cold-chain maintenance, KIIs suggest that district medical officers fail to prioritize the maintenance of cold-chain equipment. Often, transport support has not been provided to help cold-chain officers attend to cold-chain breakdowns at facility levels. Indeed, 13.1% of available vaccine storage equipment has been reported as non-functional in the surveyed facilities, with the lowest proportion being reported by hospitals (8.3%), and the highest by health centers (14.1%). Meanwhile, about 16% of facilities do not have access to a motorized vehicle for vaccine pick-up or outreach vaccination activities.

Training has also been cited as being inadequate for the cold-chain maintenance personnel. A key informant noted:

Preventive maintenance people are needed at district level. Restructuring at MOH on staff roles brought restrictions on teams on the ground who were invested in by EPI program (e.g., EHT) to handle cold-chain matters as they are now not allowed to go beyond their main roles, even though they were trained. Positions are there but unfilled. We budgeted for cold-chain training to train whoever is there, but there are not many to be trained. (National-level KII)

Indeed, only 57% of HFS respondents reported having received training on cold-chain management. The respondents varied from community health workers to clinical officers, and different types of staff. Compared to the temperature logger data, the temperature of vaccine storage equipment recorded by staff appeared out of range in a substantially smaller proportion of time (Figure 84 and Figure 85) suggesting that there are limitations in the accuracy of temperature monitors and/or that additional training may improve temperature recording.

Figure 84: Mean percent time vaccine storage equipment in or out of range, by platform of health facilities, facility chart data*

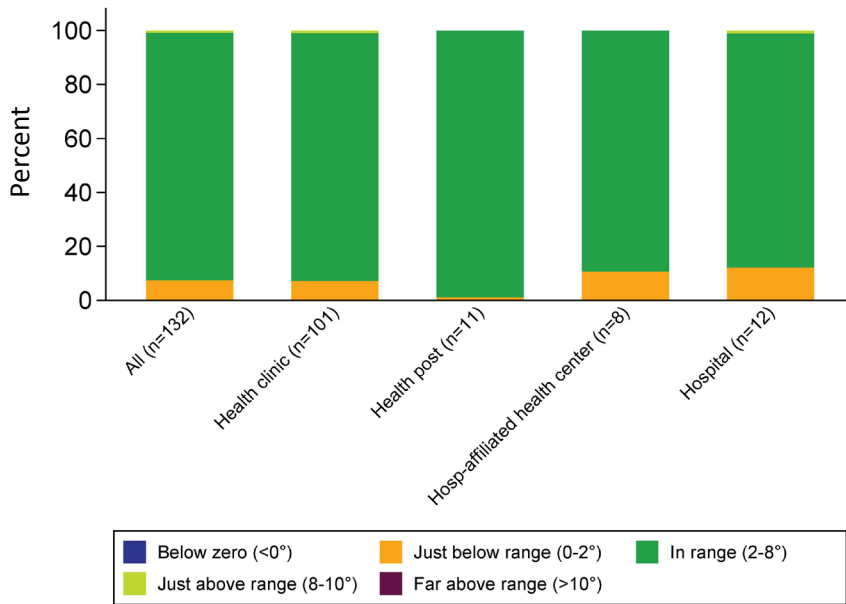
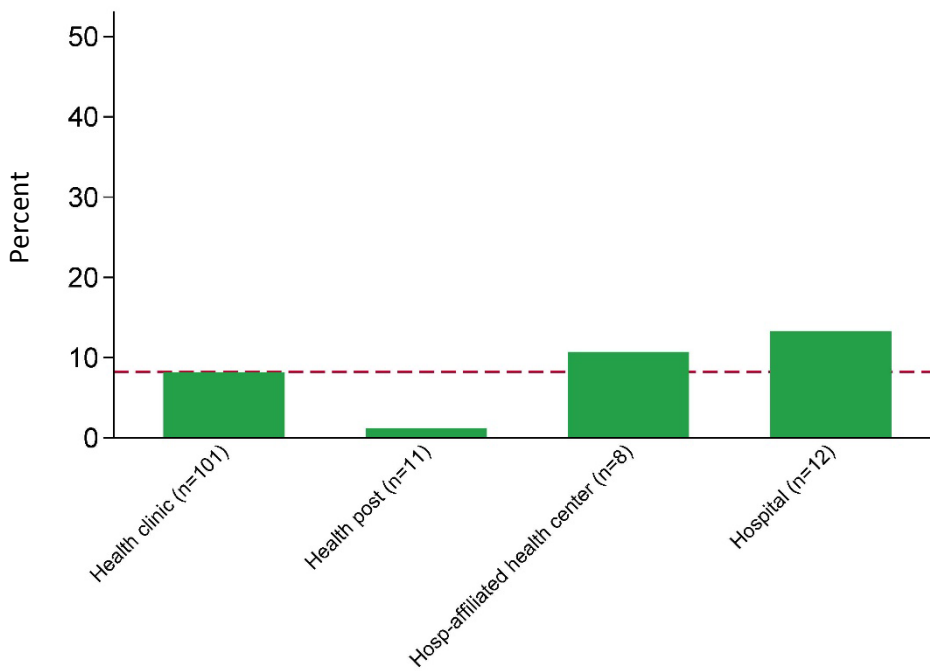


Figure 85: Mean percent of time vaccine storage equipment temperature out of range (less than 2°C or greater than 8°C) by platform of health facilities, facility chart data*



*HAHC is a hospital affiliated health center, see footnote in Table 109 for description of health facility types.

At the national level, according to our key informants, supervision and monitoring is also not prioritized for logistics and cold-chain maintenance monitoring and supervision visits.

We have noted earlier that two national level logisticians were hired and are now operating under MCDMCH (Table 33). However, this is not the case at subnational levels with the management of vaccine stocks, as the subnational levels continue to be performed by staff not specifically trained in Logistics. On the other hand, this role is performed by pharmacists, cold-chain officers and in some cases, maternal and child health coordinators who must divide their time between their primary responsibilities and vaccine stock management. These part time roles are also complicated by high turnover, with the subsequent need for retraining difficult and expensive.

Logistics capacity at national level is good to assist introduction of multiple vaccines and has been replicated at provincial level. Now more effort is required at Health Centre level as more gaps exist here. Splitting of districts also brings more demands. Old fridges need replacing – although the situation is improving. (National-level KII)

Previous Annual Progress Reports (APR) and Effective Vaccine Management (EVM) reports for Zambia mirror the mixed findings of mixed progress and remaining deficiencies as noted in this current assessment. The 2012 APR noted the modest success in improving cold-chain capacity but also noted that many newly constructed health facilities remain without equipment. A 2013 EVM progress report noted that the government of Zambia had been successful in implementation continuous temperature monitoring (a recommendation from the 2011 EVM assessment) in a limited number of cold rooms and a national- and provincial-level temperature review process; however, these processes had not been replicated at the district and facility levels. The 2013 APR notes that only about one-quarter to one-third of objectives related to cold-chain activities were accomplished with many of the incomplete items related to “increasing cold-chain equipment at peripheral levels.” Perhaps most importantly, the 2013 APR notes the risks that Zambia is taking by simultaneously introducing new vaccines and improving coverage levels of existing vaccines while struggling with limited cold-chain infrastructure.

Recommendations

- 1. In Zambia, substantial long-term investment and multi-sectorial involvement are required to develop more accurate estimates of target populations for measuring vaccine coverage and determining vaccine supply. In the nearer term, the EPI program with appropriate stakeholders, including districts, CSO and partners such as WHO and UNICEF should identify solutions to mitigate the effect of inaccurate denominators leading to vaccine stock-outs.**

Accurate estimates of the number of vaccine-eligible children are a major challenge for not only producing accurate vaccine coverage estimates, but also for determining vaccine supply, as indicated by this analysis. Data quality, including denominator issues, are an important focus of the new HSS window. A solution to this problem will likely require substantial long-term investment and multi-sectorial involvement which we strongly recommend. The EPI program with appropriate stakeholders, including districts, CSO and country partners such as WHO and UNICEF, should work on identifying solutions to reduce the effect of inaccurate denominators leading to vaccine stock-outs. In parallel, solutions to minimize the effect of inaccurate denominators on vaccine stock-outs are required. An assessment of areas prone to stock-outs should be undertaken to help in the design of potential solutions.

2. There should be continued investment in cold-chain capacity, maintenance and logistics should be a key focus on health system strengthening activities in Zambia.

Our findings from multiple sources point to the remaining challenges in the cold-chain and related logistics and supervision that have affected vaccine delivery, specifically stock-outs. Cold-chain problems are likely to have other downstream effects on vaccine viability and effective immunization. This later consequence is an important area of follow-up as part of the household survey data collection to measure vaccine antibodies. We recommend that this be a continued focus of broad partner support beyond Gavi. Specifically, we recommend that government and partners consider the following areas as specific areas of investment:

- Expand cold-chain capacity in facilities and districts prone to stock-outs to allow for increased buffer stocks.
- Consider increasing the use of solar refrigerators to address the issue of erratic power supplies particularly for facilities presently using kerosene and gas refrigerators.
- Establish dedicated positions for logisticians to be put in place and appropriately qualified personnel hired at provincial and district levels.
- Strengthen monitoring and supervision of vaccine supply and logistic at subnational-levels.
- Provide regular training of personnel in logistics and cold-chain management and equipment maintenance

Robustness of finding

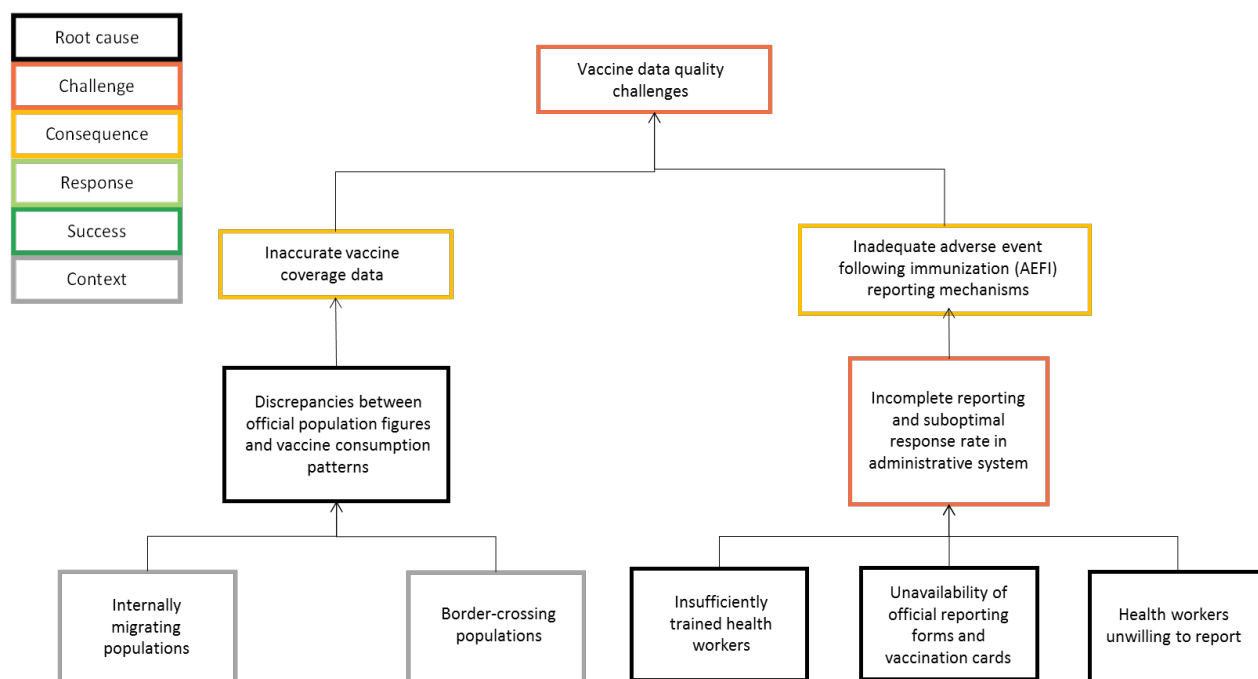
Finding	Robustness Ranking	Rationale
Discrepancies between vaccine consumption and official target population figures that are used to determine vaccine supply, remaining cold-chain inadequacies at facilities, and lack of adequate planning and vaccine stock management at the subnational level contributed to stock-outs of both PCV and rotavirus vaccines.	A	Information was gathered from different methods and high quality data sources, specifically the HFS representative sample of health facilities. Many of the findings from the process evaluation were triangulated with data collected through the HFS. Specifically, our findings around vaccine stock outs, cold-chain inadequacies, lack of maintenance of vaccine storage equipment were triangulated from the different data sources used.

Finding 2

Ongoing limitations of the vaccine surveillance system, including lack of tools and forms at facility levels, inaccurate denominators, insufficient health worker training, and incomplete reporting limit the ability of the EPI program to track the roll out of PCV and rotavirus vaccine in terms of vaccine coverage, adverse events, and other indicators.

Another key challenge identified by the evaluation is the ongoing limitations of the vaccine surveillance system. The causes of these challenge are summarized in (Figure 86) and described in further detail below.

Figure 86: Root cause analysis of vaccine data quality challenges



The first underlying cause of inaccurate vaccine coverage data is common to the first finding, which concerns discrepancies between official population figures that are used as the denominator for vaccine coverage. These were covered in detail in the previous section and are not repeated here.

A second underlying cause is incomplete reporting of vaccine doses delivered. In many facilities, tallying of doses delivered is absent, incomplete, not sufficiently verified, or not completed on time. For instance, in the case of PCV and rotavirus vaccine, several months of data were missing from HMIS forms at surveyed facilities (Figure 87 and Figure 88).

The underlying causes of these problems are several. Many facilities do not have official forms to report administered vaccine doses (Figure 89). Additionally, in many facilities, health workers do not have the training to perform the function of filling out the HMIS forms. The shortage of health workers affects the time that is dedicated to filling out the tally sheet. These problems have led to inaccurate estimates of vaccine coverage, included estimates of coverage above 100%. These challenges do not only affect the

surveillance of PCV and rotavirus vaccine, but all vaccines, given that availability of forms, and training of health workers, and their availability, are relevant to the surveillance of all vaccines.

Incomplete reporting is also a primary cause of data quality issues for the reporting of adverse events following immunization (AEFI). AEFIs are a crucial indicator for vaccine monitoring and evaluation given the financial and public health impact they may have. This is especially relevant in the case of newly introduced vaccines, as the introduction is the population's first exposure to the vaccine. Reporting on AEFIs was found inadequate following the introduction of PCV (as noted here and in the previous 2013 Gavi FCE report) and rotavirus vaccine in Zambia, and three factors were identified as root causes for this inadequacy. First, similarly to the case of delivered doses of vaccine, a large number of facilities were found to not have an AEFI reporting system in place, or official reporting forms available on premises (Figure 89). Second, according to the health facility survey, not all health workers available at facilities have received training to identify and report AEFIs. Third, our key informants revealed that possible perceptions of incompetence or negligence as the cause of AEFIs make health workers reluctant to report AEFIs. These findings are similar to what we reported last year from KIIs. In last year's report, we noted concerns about availability of reporting forms in facilities, as well as lack of information among health workers on the importance of reporting, specifically AEFIs. Even further, the comprehensive program review in 2014 reported on challenges to vaccine surveillance data. The report points to weak linkages between HMIS (MOH) and routine immunization service delivery (MCDMCH) as a major cause behind these challenges. The EPI program and surveillance do not regularly have access to HMIS data.

These challenges render difficult for the EPI program and country partners to properly monitor and assess how well routine and new vaccines are being delivered to the population and the adverse events associated with them.

Figure 87: Months of PCV data missing from HMIS by PCV dose, April 2013 to May 2014

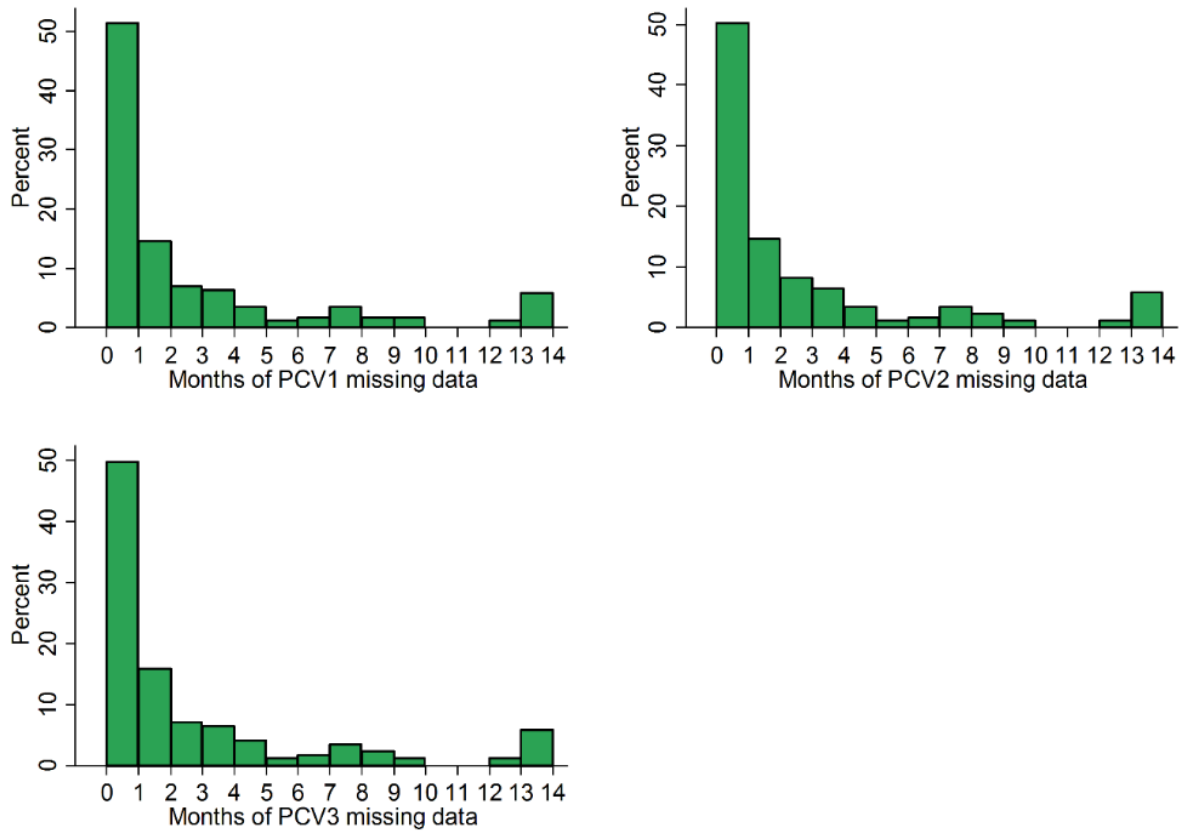


Figure 88: Months of rotavirus vaccine data missing from HMIS by vaccine dose, November 2013 to May 2014

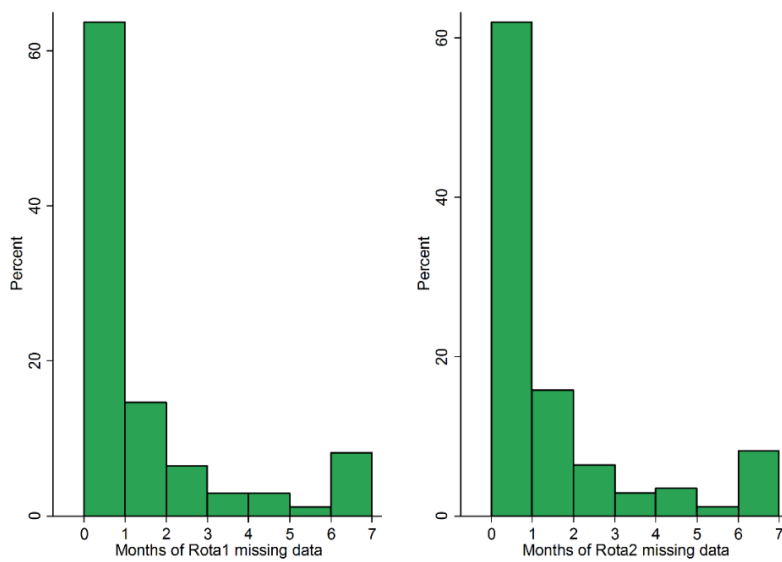
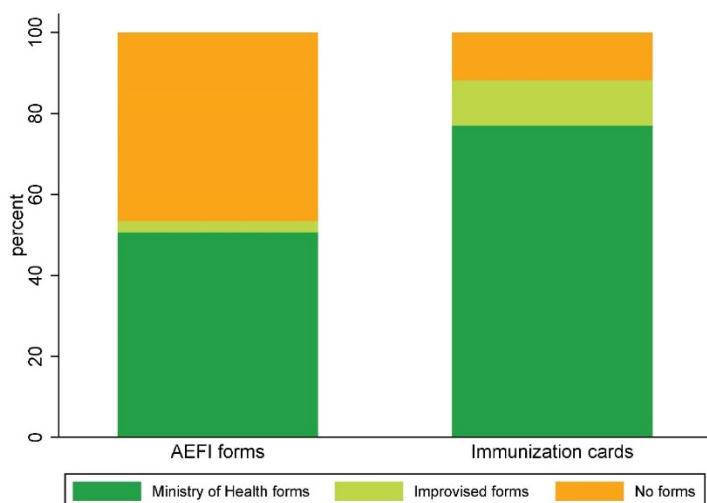


Figure 89: Availability of reporting forms at health facilities (percent of facilities with official AEFI forms [left] versus official immunization cards [right])



Recommendation

- 1. Data quality is a key focus of the latest HSS support stream. Consistent with this focus and the findings of the evaluation, the upcoming application for HSS in Zambia should include substantial investments to address the issue of data quality, including ensuring availability of forms and tools, as well as training to ensure accurate reporting.**

Vaccine surveillance is crucial for a country to monitor its vaccine delivery programs, and assess the unintended negative consequences of vaccines, namely AEFIs. However, the vaccine surveillance system in Zambia was weakened due to many factors, including incomplete reporting and unavailability of reporting forms. Given the focus of HSS specifically on improving vaccine data quality, the application should give special consideration for improving vaccine data quality in Zambia. The currently identified responses for the HSS include measures to improve data quality. These responses should include sufficient investments to ensure the availability of forms and tools at facilities and health worker training to improve reporting quality.

Robustness of finding

Finding	Robustness ranking	Rationale
Ongoing limitations of the vaccine surveillance system, including lack of tools and forms at facility levels, inaccurate denominators, insufficient health worker	A	Information was triangulated from different methods and data sources. The findings on reporting, availability of forms, and health workers training were

training, and incomplete reporting limit the ability of the EPI program to track the roll out of PCV and rotavirus vaccine in terms of vaccine coverage, adverse events, and other indicators.

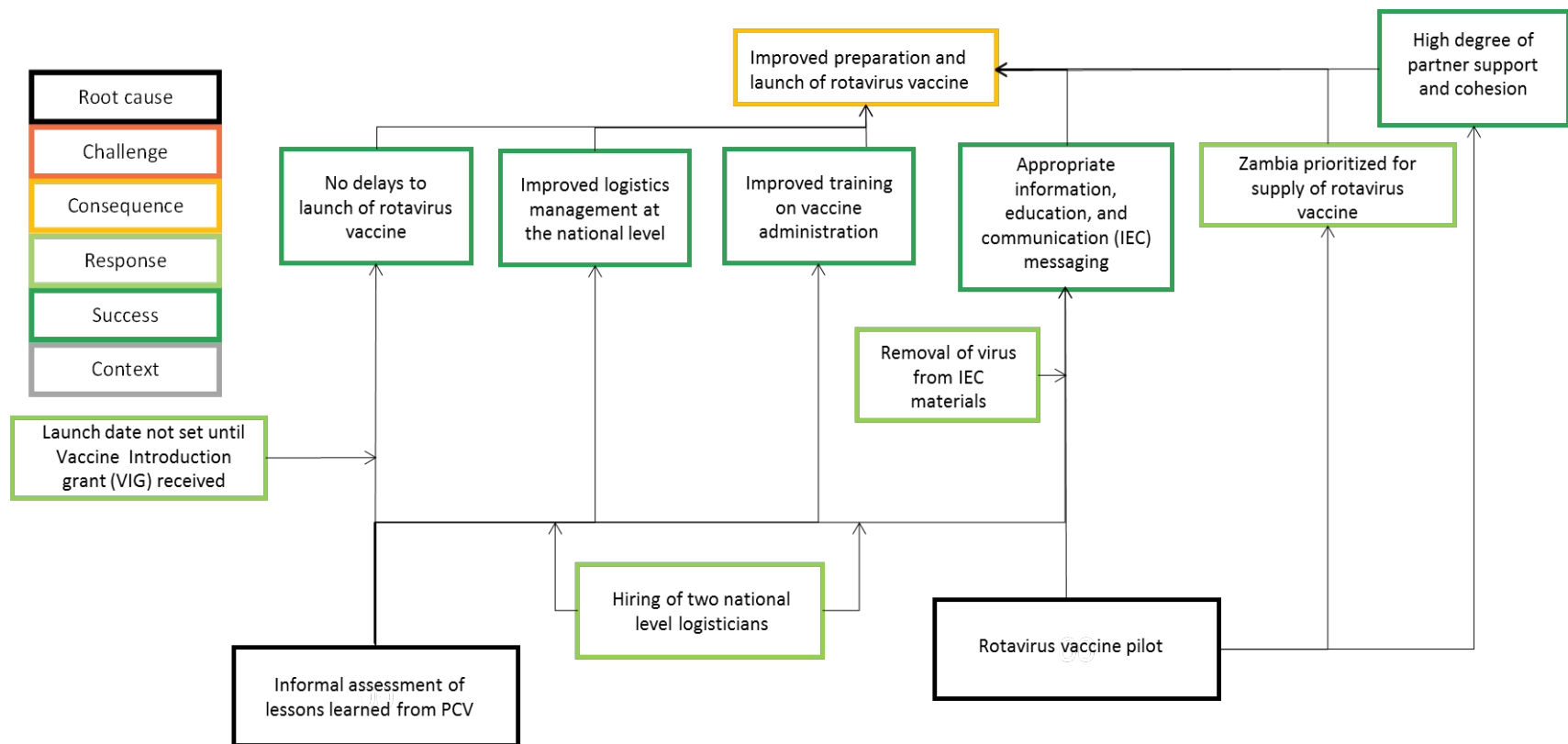
triangulated from the different data sources used.

Finding 3

Experience gained through the pilot implementation of rotavirus vaccine in Lusaka province and adaptations based on informal lessons learned during the launch of PCV in 2013 contributed to improved preparation, launch, and roll out of the rotavirus compared to previous introductions. A formal PIE and a longer time period between the introductions could have potentially allowed for greater learning and opportunity to address past limitations prior to the rotavirus vaccine introduction.

As noted earlier in this section, the analysis of HMIS data and our overall evaluation of the implementation process, preparation, and introduction of rotavirus vaccine was comparatively smoother than that observed and reported on for PCV in the 2013 report. Figure 90 summarizes our analysis of the underlying factors that contributed to the improved introduction.

Figure 90: Root cause analysis for the improved preparation and launch of rotavirus vaccine



The first underlying factor was the use of the pilot implementation of rotavirus vaccine in all the districts in Lusaka province to provide valuable lessons that guided preparations for the national launch of the vaccine. According to informants, the pilot provided an opportunity to accelerate the introduction of rotavirus vaccine in Zambia. Not only were they able to use lessons learned to address gaps in the program and inform the national roll out, but also to facilitate Zambia's prioritization to receive vaccine stock. There was limited global supply of rotavirus vaccine, but because of the pilot, Zambia was prioritized to receive sufficient vaccine to avoid stock-outs in the three pilot districts.

The pilot was an opportunity to accelerate the introduction of Rotavirus vaccine into the national immunisation schedule – as we were to use lessons learnt to inform national roll-out. It helped to address gaps that were identified as well as to accelerate prioritisation of Zambia's introduction of Rotavirus vaccine (there was limited supply of Rotavirus vaccine at global level and thus the pilot helped Zambia to get priority with these limited supplies). (Government KII)

Implementation of the rotavirus vaccine pilot in Lusaka province was led by CIDRZ as a component of their Program for Awareness and Elimination of Diarrheal Disease. Following the pilot, CIDRZ played a more prominent role in preparing for the national launch and roll-out than they have done for previous vaccine launches. During the pilot, CIDRZ made a concerted effort to involve and consult with various stakeholders. As a result, country partners were clear on their respective roles and responsibilities for the national roll-out, in many cases based on their involvement in the pilot. Consequently, informants pointed to a high degree of cohesion and coordination between partners in preparing for the national launch and roll-out, particularly when compared to the implementation of other streams of Gavi support. This has eased the burden on the government in preparing for the national introduction. According to a government key informant:

With PCV we were highly dependent on the UN, there was a bigger pool of stakeholders with Rota.

Additionally, trainers for the national level roll out gained firsthand experience administering rotavirus vaccine during the pilot. They were perceived by informants as being more knowledgeable about the vaccine and its administration in health facilities, thereby making them more effective trainers.

Information, education and communication (IEC) materials used in the national roll-out benefited from testing during the pilot. For instance, during the pilot stakeholders learned that using the term *rotavirus* was problematic because communities tended to associate any virus with HIV/AIDS, widely known to have no vaccine or cure. As such, in developing IEC materials for the national launch, a decision was made to avoid the use of virus in any materials, instead referring to "rota vaccine."

During the pilot, CIDRZ identified a lack of dedicated logisticians to manage vaccine stocks at the national and subnational level as an important gap and facilitated the recruitment of a national level logistician. This learning informed the rotavirus vaccine launch and is considered to have helped improve the management of vaccine stock at the time of rotavirus vaccine launch. As a consequence, rotavirus vaccine introduction was expected to have fewer or no stock-outs compared to PCV, which did not have the opportunity to benefit from the learning of a pilot. A national-level partner informant stated:

There were a lot of avoidable vaccine stock-outs [with PCV] which were attributed to staffing challenges at CHU. (National-level partner KII)

Another positive implication of this is that MCDMCH soon followed suit, recruiting a second national-level logistician and filling a position that had long been vacant. However, as noted earlier in this report, the lack of trained logisticians at the subnational level remains a persistent challenge.

We highlight that informants also noted the difficulties with fully replicating lessons learned during the pilot in the national rollout due to such factors as funding constraints, different work environment in the government compared to NGOs, and human resource capacity constraints both in terms of number and skills of personnel. The pilot was done at a smaller scale, where it was easier to provide all the necessities for implementation, such as skilled human resource and logistical support. These may not always be feasible at the national level as noted by a key informant:

NGO implemented program versus government implementation very different. So things that were well done with CIDRZ don't apply when government takes over. When it comes to national roll outs, different challenges come out. Some districts don't have things in place. Scalability at the national level needs to be seen with different perspective and with more reality. (National-level partner KII)

Further, the pilot lessons learnt and experience was not documented at the time of the national roll out and these had so far been shared through meetings, which could have limited the effectiveness of sharing lessons and how easily they could be replicated.

CIDRZ are currently doing evaluation of the pilot. [We] got updates through TWGs and other meetings. No formal reports have been submitted on the pilot and we are awaiting the evaluation report, once it is finalised. (Government KII)

A second underlying factor identified as contributing the smoother introduction of rotavirus vaccine was that, although no formal assessment was conducted between the PCV/MSD and rotavirus vaccine introductions, the national launch and roll-out of rotavirus vaccine benefited from informal lessons learned during the introduction of PCV. A joint PIE for PCV and rotavirus vaccine was conducted in July 2014, one year after the introduction of PCV. As noted in the previous 2013 report on PCV introduction, a PIE of the simultaneous introduction of PCV and MSD prior to the rotavirus vaccine introduction would have led to more formal learning to improve the rotavirus vaccine introduction. Unfortunately, the short time span between the two introductions limited the ability to conduct the PIE.

However, lessons learned from PCV were incorporated on a more informal and *ad hoc* basis. For example, the PCV case report highlighted the negative implications of repeated setting and resetting of the launch date, in that case largely attributed to the delayed arrival of the vaccine introduction grant and the delayed transfer of these funds from UNICEF to provincial and district offices. The EPI program learned from that experience; instead of risking repeated delays by setting a launch date early in the planning process and communicating this widely, they were adamant that they would only commit to a date once the VIG had arrived in country. By doing so they avoided the numerous rescheduling and resulting uncertainty encountered in the period leading up to the eventual launch and roll out of PCV.

Although some informal lessons were learned and implemented, it is also important to note that the insufficient time period between introductions limited not only the ability to conduct a PIE but also to

implement even those informal lessons learned. For example, even with knowledge of inadequacies in the PCV introduction, for example in the cold-chain, it was very difficult for the EPI program and country partners to make significant improvements during the restricted time frame.

Recommendation

- 1. EPI programs, country-partners and Gavi should ensure that learning experiences are maximized for new vaccine introductions. Learning from previous introductions should be based on robust post-launch monitoring and evaluation, including post-introduction evaluations. This should also include sufficient time between introductions to allow corrective actions to be taken. Another option is to explore further the use of phased introductions such as through the use of pilot or demonstration projects that provide opportunities for early identification and resolution of bottlenecks and partnership strengthening.**

Learning can be first retrospective. For instance, countries can learn from one introduction to the next by conducting post-launch activities ranging from supervisory visits and post-introduction evaluations, which provide critical feedback on needed programmatic improvements. In doing so, it is important to leave sufficient time between introductions to maximize learning. In Zambia, a formal PIE was not conducted between the introduction of PCV, MSD, and rotavirus vaccine introductions due to time constraints. While some lessons learned were informally incorporated towards the rotavirus vaccine introduction, there were a range of other issues identified as part of the PIE, including cold-chain inadequacies and training which could have been improved as part of the rotavirus vaccine introduction. Our findings also highlight the importance of not only leaving sufficient time for post-introduction evaluation but also time to implement lessons learnt. For example, even though the EPI program and country partners were cognizant of remaining cold-chain inadequacies, there was insufficient time to address these between the two vaccine introductions.

Learning can be prospective as well. As shown in the evaluation work, the pilot for rotavirus vaccine provided a number of benefits that led to improved roll-out and implementation of the vaccine at the national level. This included a partial expansion of the cold-chain, improving the logistics management at the national level, leveraging the experience of health workers in the pilot areas as trainers and the appropriate adaptation of IEC materials. Perhaps most importantly the pilot contributed to a strengthened partnership supporting the rotavirus vaccine introduction, with many parties involved reporting greater clarity on roles and responsibilities. Given the positive experience of the rotavirus vaccine pilot in Zambia, country governments, partners and Gavi may consider taking a phased approach to introducing new vaccines elsewhere, providing an opportunity to identify and address any systems bottlenecks, and to strengthen partnerships, prior to national roll-out. The first phase of the introduction should be promptly evaluated to determine readiness for scale up of the vaccine introduction. Phased vaccine introductions might be particularly useful in challenging settings, for example, in countries with sizeable or diverse populations.

Robustness of finding

Finding	Ranking	Rationale
Experience gained through the pilot implementation of rotavirus vaccine in Lusaka province and adaptations based on informal lessons learned during the launch of PCV in 2013 contributed to improved preparation, launch, and roll out of the rotavirus compared to previous introductions. A formal PIE and a longer time period between the introductions could have potentially allowed for greater learning and opportunity to address past limitations prior to the rotavirus vaccine introduction.	B	The information was triangulated from different methods and data sources of good quality, such as the HFS representative sample of health facilities. Specifically, HFS data were used to capture vaccine expansion following launch date and compare rotavirus vaccine delivered doses to those of pentavalent vaccine.

Health system strengthening

The government of Zambia began to implement the initial Health system strengthening (HSS) grant program in 2008. However, the program could not be completed due to alleged financial irregularity in the Ministry of Health, which led to the freezing of funds. Later, the government of Zambia was given the option to either reprogram the grant for the undisbursed funds or submit an application for a new grant. The government opted to submit a new application. An Expression of Interest (EOI) to apply for Gavi support for HSS was subsequently made in May 2014. The government was targeting to submit the application in the September 2014 application window. However, this date was not met and the application was expected to be submitted in January 2015.

Summary of progress

Table 37 summarizes the progress made in the application of the HSS grant. It highlights the challenges the process has faced or continues to face as well as successes that have been recorded. The application was initially scheduled for submission in September 2014, but was later rescheduled to January 2015.

Table 37: Progress of Health system strengthening support

Milestone Heading	
<i>Progress and successes</i>	<i>Challenges and responses</i>
Critical bottlenecks identified	
<ul style="list-style-type: none"> - A stakeholder orientation workshop was held in April 2014 at which bottlenecks for the HSS application were identified. The workshop was attended by 18 attendees representing government and a broad range of country partners, including the FCE team and facilitators from WHO Regional Office and WHO Country Office (<i>document review, KII, meeting observation</i>). 	<ul style="list-style-type: none"> - There is limited data to support the identified bottlenecks (<i>document review, meeting observation</i>). - Process of identifying bottlenecks seems top-down with little obvious engagement from district or provincial stakeholders as there were no participants from these levels at the workshop (<i>document review, KII, meeting observation</i>). - Seven bottlenecks were considered for this application: 1) reduced utilization of immunization services; 2) issues in procurement and supply chain management; 3) poor data quality and analysis and utilization; 4) inadequate health worker skills and capacity; 5) low community and CSO involvement; 6) health financing challenges; and 7) weak governance around EPI implementation (<i>meeting observation, document review</i>).
Appropriate responses identified	
	<ul style="list-style-type: none"> - Appropriate responses were broadly outlined but needed further clarification and detail. These responses were reached through consensus between partners attending the workshop, and 1) improve access and sustainable utilization of immunization services in populations with large numbers of un-immunized children; 2) ensure that health facilities have the appropriate amount of

	<p>listed vaccines with correct potency by 2019; 3) strengthen the HMIS by improving timeliness and completeness of data collection analysis and utilization at all levels; 4) strengthen the capacities of health workers to deliver immunization services at health facility-level by 2019; 5) strengthen community structures and CSOs in order to participate in and promote EPI services by 2019; 6) improve accountability and availability of funds at district and health facility levels; and 7) improve institutional governance mechanisms and financial management systems (<i>meeting observation, document review</i>).</p>
<p>Adequate plans developed in time for application submission</p>	
<ul style="list-style-type: none"> - A roadmap outlining key activities and the lead partner was developed during the April workshop (<i>document review, KII, meeting observation</i>). - An EOI was submitted to Gavi, targeting a September 2014 submission of the HSS proposal (<i>document review</i>). 	<ul style="list-style-type: none"> - Although lead partners for key activities were established during the workshop, there were lapses in the fulfillment of said activities due to leadership, communication and coordination challenges (<i>document review, KII</i>).

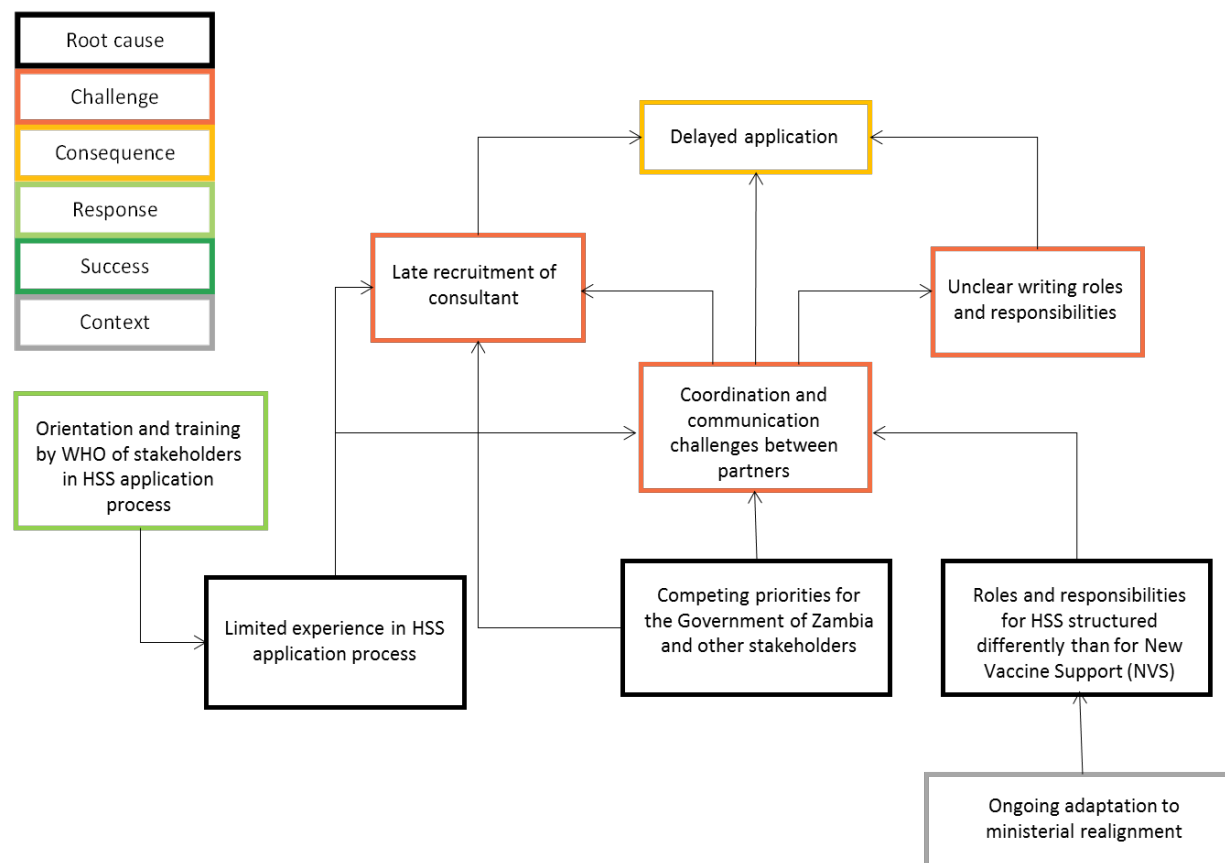
Analysis of findings

In this section we evaluate the progress of Zambia in introducing HSS funding thus far, and offer findings and recommendations based on work thus far.

Finding 4

Coordination challenges stemming from the different partnership structure for HSS compared to new vaccine introductions, limited experience with the new HSS application process, and multiple competing priorities led to a revision of the timeline for the HSS application submission from September 2014 to January 2015.

The development and submission of the HSS application was initially targeted for September 2014 but was later revised to a projected submission of January 2015. Our analysis identifies a number of key explanations for the shifting timeline.

Figure 91: Root cause analysis of the delayed HSS application

The first key root cause identified was that the allocation of roles and responsibilities in developing the HSS application are structured differently than for other streams of support (i.e., NVS). For instance, while CHU leads the development of applications for new vaccine support, they play a *supporting* role with HSS, providing technical inputs. And while the Department of Planning and Information (DPI) is included in the new vaccine application process, they are intended to *lead* the development of the HSS application. So while the set of organizations included in the HSS proposal development process is for the most part consistent with other streams of Gavi support, the allocation of roles, and the overall management structure, are different. This then contributed to the coordination challenges as communication flows and decision making structures were less familiar to all parties involved.

While an initial workshop involving representatives from CHU, DPI, WHO, UNICEF, Churches Health Association of Zambia (CHAZ) and Catholic Relief Services (CRS) was held in April, 2014 in Chaminuka to develop a roadmap for HSS proposal development, momentum was lost following the workshop, possibly reflective of unclear allocation of roles and responsibilities and an absence of a management structure for the partnership. Specifically, the group was unable to meet as scheduled to develop a more detailed plan of action outlining contributions to the proposal writing process. Accompanying this were communication challenges that were reflective of less-developed partnerships. For instance, the

decision to revise the submission timeline was not communicated to all involved parties in a timely manner and some informants reported that there was insufficient consultation about the revised application submission date. Some informants noted that, although they had heard rumors of a delay, they did not follow up because they did not want to be perceived as “hijacking the process.”

[We] tried to follow up on cancelled meeting from MCDMCH to discuss the roadmap, but CHU seemed to think it was the Department of Planning who should take the lead. Not clear who from that department is going to push this initiative through.
(National-level partner KII)

Our interviews also suggest there was a lack of clarity around the time and steps required to recruit an international consultant to provide technical assistance in writing the proposal and this was not initiated in a timely manner.

A second root cause identified was the limited experience in the HSS application process. This is particularly the case for DPI, which had not been significantly involved with previous applications for new vaccine support from Gavi. It should also be noted that there have been major changes to the HSS guidelines in comparison to the previous application by Zambia and as a result, even those who have worked on the previous application were unlikely to be completely familiar with the revised process. Challenges with guideline revisions were also noted with the previous HSS tracking study.³⁷ Recognizing the limited capacity and experience with the HSS application process, WHO organized a capacity-building and orientation workshop for MCDMCH and key stakeholders to orient them to the new application guidelines and to train the team on the Gavi budgeting template and the M&E framework. While this was an important response, key informants acknowledged that there was still a need to build additional capacity around the Gavi HSS application process.

We need support or orientation in the process, something more detailed and in depth. The Chaminuka orientation [capacity building and orientation workshop] did not cover all the areas and tended to be general. We need one especially after working on the application. (Government KII)

A third root cause was that there were a range of competing priorities during the period of proposal development. Development of the HSS application conflicted with other activities, most notably the annual budgeting cycle by DPI and the post-introduction evaluation of PCV/MSD and rotavirus vaccine and application for IPV support by CHU.

The overall downstream effect of these causes was a stalled application process and a new target date for submission of January 2015 was set.

Recommendation

1. MCDMCH should identify a dedicated point person within Department of Planning and Information to coordinate the application of the HSS grant in Zambia.

Our evaluation identified that coordination between stakeholders involved in the HSS application was a limitation in the application process. With the broader range of stakeholders involved in the HSS application and implementation as compared to other EPI activities and the challenges of coordination

and communication within this partnership, we recommend that MCDMCH identifies a dedicated point person within DPI to coordinate the application of the HSS grant in Zambia

Robustness of finding

Finding	Robustness Ranking	Rationale
Coordination challenges stemming from the different partnership structure for HSS compared to new vaccine introductions, limited experience with the new HSS application process, and multiple competing priorities led to a revision of the timeline for the HSS application submission from September 2014 to January 2015.	C	The information was gathered from a limited number of qualitative data sources. Because the application process is still ongoing, it is too early to draw broad conclusions and this topic requires additional investigation in the coming period.

Inactivated polio vaccine introduction

The government of Zambia through MCDMCH submitted an EOI for IPV to the ICC for endorsement on May 14, 2014. The ICC approved the EOI, following which a six-member team comprising MCDMCH (DPI and CHU) and the two traditional UN partners namely, WHO and UNICEF, began preparing the full IPV proposal. The full application was submitted on September 15, 2014. Technical support was provided by WHO, UNICEF in September 2014, through a regional workshop for the development of IPV applications. We further note that the IPV application was developed and prepared within a short period of time during the period mid-May to early September of 2014. The revision of the cMYP was finalized in early September 2014 which included, among things, the introduction of IPV in 2015.

We observe that no updates about the IPV application process was made available during the technical working groups. Therefore, the FCE team will investigate the IPV decision and application development process in the near future. For example, it remains unclear how the decision was made to focus on IPV during this period, and at what level of decision making within the government. The influence of government of Zambia and global stakeholders and international stakeholders in this application remains a key area of follow-up. The preparation of the HSS proposal was expected to go on during this same period. Hence, it is necessary to understand whether the time and resources devoted for IPV affected the preparation of the HSS proposal given that the core team was the same for both applications. Second, the extent of stakeholder consultation in the proposal development is also an area for follow-up. It is important to understand if any technical assistance required was deemed necessary and sought out. Given the global momentum around IPV introduction, it is of interest to know how the global trend may have influenced the pace and manner by which the decision on IPV was made. These elements of the introduction will be followed up in planned upcoming KIIs.

Cross-stream analysis

Across the various streams of funding, there were a range of elements that contributed to successes and challenges in the implementation of Gavi support in Zambia. From these we have identified a number of common issues across streams that revolve around four main domains: data, human resources, cold-chain, and partnership.

Vaccine data quality

Data issues affected the availability of vaccine, the accurate surveillance of vaccine coverage and AEFIs. The total volume of vaccines received by the government of Zambia, and the allocation of these vaccines to districts and facilities is based on official CSO figures of vaccine-eligible children. However, the patterns of vaccine consumption differ from these figures as many populations migrate seasonally within Zambia, individuals seek healthcare, including vaccination for their children, outside of their health region, and children from neighboring countries are brought to Zambian health facilities to be vaccinated. Hence, many health facilities had a higher demand for vaccine than the amount originally allocated, and with the unavailability of vaccine transportation vehicles or the lengthy vaccine order and deliver process, vaccines were stocked-out in the facilities.

Furthermore, data quality of vaccine administration was suboptimal due either to lack of absent or incomplete reporting, or absence of official forms for vaccine and AEFIs. Data on vaccine administration was missing for certain periods in HMIS at many facilities. In parallel, official forms were not available in a significant proportion of health facilities. As for AEFIs, some facilities did not have a system in place to report them, or health workers avoided reporting them in fear of being the cause behind the adverse event.

HSS provides one opportunity to address these vaccine data quality challenges, including strengthening HMIS through system expansion, training, data management and analysis. Indeed, data quality is a stated priority for HSS. The FCE will track the extent to which these challenges are addressed as the HSS application is developed and submitted.

Human resources for health

Human resources for health have remained a challenge across all funding streams to varying degrees. Shortage in required health workers were in both quantity and skills of required health workers and the effect of this shortage has been observed at various levels. At the national level, the few program staff at MCDMCH were overburdened with many competing priorities. For instance, during the period of May to September 2014, two parallel application processes were ongoing: HSS and IPV. In part, because of limited capacity, HSS was stalled while IPV was submitted. Other competing priorities included the post introduction evaluation of PCV, MSD and rotavirus vaccine.

The hiring of two national level logisticians with support from CIDRZ helped ease the burden of logistics management on other staff and improved logistics management generally at the national level. However, the absence of logisticians at the subnational level means there still exist gaps in logistics management at the subnational level. Indeed, there is a recognized deficit in the number of required health care workers that are required to implement the EPI program, including cold-chain personnel,

logisticians and nursing staff. With this shortage of staff, many have to take on multiple roles. For instance, pharmacy staff and MCH coordinators are having to take on cold-chain logistics' matters. Training the various staff at subnational level in multiple areas is also a challenge, further complicated by the relatively high staff turnover at this level, meaning that even when training is provided the expertise is lost when the staff member moves away and others take their role.

These factors are not unique to the EPI program, but rather affect the entire health system. Our early analysis suggests that building capacity of health workers through training may be an area of investment for HSS. However, this does not address the broader capacity issues of available human resources (at all levels) which are likely to still be insufficient.

Cold-chain

There is clear evidence of persistent inadequacies in the country's cold-chain capacity as pointed out by several methods and by previous assessments. Zambia has seen accelerated expansion of the cold-chain in the past two years. Significant partner support has been forthcoming to help expand the cold-chain capacity in the country. In particular, JICA and CIDRZ have been instrumental in supporting the procurement and installation of cold-chain equipment at both the national- and subnational-levels.

Despite these efforts, the evaluation pointed out some severe persistent challenges faced by the cold-chain in many districts in Zambia. The limitations in cold-chain described earlier have incapacitated the effective management of vaccine stocks in general. Erratic power supply, lack of timely maintenance services, and the absence of vaccine storage equipment in many facilities have contributed to the failure to stock vaccines in many facilities, thereby interrupting the immunization service delivery.

On a more optimistic note, challenges faced by the cold-chain are noted as critical bottlenecks in the health system delivery in the HSS application under development and are likely to be an area of further investment in the coming years. Indeed, vaccine introduction grants did not prove enough to solve the cold-chain problems, hence the relevance of the HSS grant. A successful application for HSS will provide a great opportunity for the improvement of the cold-chain capacity in the country. This will in turn lead to improvements in the management of vaccines and the smooth operation of the EPI program with less interruption in cold-chain and vaccine stock.

Partnership

Partnership emerged as a key theme that contributed to the successes achieved within some streams of support, and challenges realized in the context of others. For instance, a number of key informants noted that clarity in roles and responsibilities of partners (including the relevant ministries and other country partners) in preparing for and launching rotavirus vaccine was crucial to the relatively smooth launch and roll out. A couple of explanations were offered. First, because there was a pilot of rotavirus vaccine, partners developed a clearer understanding of their respective roles as they prepared for the national launch, based upon their roles in the pilot, and learning gained through that effort. And second, informants attributed this success to the role of CIDRZ, who played a leadership role in not just the implementation of the pilot, but also in supporting MCDMCH in preparing for the national roll out.

By contrast, a lack of clarity in the roles and responsibilities of partners in developing the HSS application was identified as a barrier to submitting the application as originally planned in September, instead postponing submission to January 2015. Though a road map for the HSS application was developed in April at a meeting attended by relevant partners, weak coordination and communication between partners following the April meeting was identified as a key factor contributing to the delayed development and submission of an application for HSS.

The value add of the Gavi partnership at the country level is a key evaluation theme for evaluation, and given its recognized contribution in the context of the new vaccine and cash-based streams of support, is a key area for further investigation in 2015, particularly with HSS application development ongoing.

Conclusions

A number of conclusions can be drawn from the Gavi FCE in Zambia. First, in 2013, Zambia introduced three new vaccines with support from Gavi (PCV, MSD, and rotavirus vaccines) and both PCV and rotavirus vaccine were routinized fairly quickly following their respective national launches. The scale-up of rotavirus vaccine was notably faster than for PCV. At the subnational level, PCV and rotavirus vaccine were well-received and integrated into the local immunizations programs and their delivery benefited from annual government planning and budgeting.

In addition, Gavi support is also generally well-aligned with the country's priorities as described in the national health strategic plan and the cMYP and contributes to Zambia's priority of accelerating reduction in child mortality. Furthermore, the cMYP was revised to include IPV just prior to the application for Gavi support. In terms of PCV and rotavirus vaccine, pneumonia and diarrhea are leading causes of child deaths in Zambia, hence, the introduction and routinization of these vaccines are likely contributing to the country's efforts toward reducing child mortality.

Second, Gavi support to Zambia is implemented with a network of local partners. All planning and implementation activities have been undertaken with support from country partners. Gavi's support has played a catalytic role in securing support from local donors to support cold-chain and other components of the EPI program. For instance, support from JICA and CIDRZ for cold-chain is well documented. National logistics planning and management was boosted by the addition of two national level logistician based at CHU, one of whom was funded by CIDRZ. Our evaluation suggests that there was a stronger and broader partnership around the rotavirus vaccine introduction compared to previous introductions. This partnership is an important focus of the Gavi FCE and will be covered in further depth in later reports.

Third, despite the several positives highlighted in the report, a number of challenges in the EPI program remain and fully reaching the target population is constrained by persistent deficiencies of the immunization system. As highlighted in the report, monitoring and demand forecasting are hampered by data quality issues such as inaccurate target populations. Although the cold-chain was expanded around the introduction of PCV and rotavirus vaccine, it remains inadequate at the subnational-level and is compounded by breakdowns in cold-chain either as a result of faulty equipment or unavailability of power or fuel. Logistics planning and management at the subnational-level are hampered by the lack of trained logisticians. These are also reflective of an overall shortage of staff to deliver immunizations.

Most health facilities, especially the rural-based one, are run by too few trained health workers, a situation which has constrained the expansion of the EPI program through increased outreach activities. For instance, facilities have failed to conduct successful outreach activities because there is only one staff who has to operate the facility. Central level capacity to managed and implement new introductions alongside routine and campaign-based demands also remains limited with a small number of staff dedicated to these roles. The vaccine introduction grant provided by Gavi remains inadequate to cover all these deficiencies, and these are all key areas of focus that we recommend for health system strengthening activities, especially the upcoming HSS application.

Finally, there is limited use of monitoring and evaluation tools to inform policy and program performance. There is little regular feedback from the surveillance unit situated at the University Teaching Hospital to the planning department in the MCDMCH. During the TWG meetings, there is less emphasis on accessing regular reports from administrative to facilitate monitoring of program performance, and to inform program implementation. This likely relates to the perception of low data quality, which limits their use; this is an important area for future investment. Challenges of routine immunization are many which require an effective M&E system to provide timely, reliable and accurate information.

Positive and negative unintended consequences of Gavi support in Zambia

One positive unintended consequence of new vaccine support was that it stimulated local donors to provide funding to the EPI program. Funding for cold-chain expansion, support for surveillance for diarrhoeal diseases, and funding for national level training were examples of this support.

While the introduction of several new vaccines by Zambia with the support of Gavi over a short time period was a notable achievement, this support had an unintended consequence. Although key informants emphasize the role of the new vaccine introductions in averting the burden of vaccine preventable diseases, there was insufficient time to undertake any formal evaluation of the PCV/MSD introduction to inform the introduction of rotavirus vaccine. For example, while implementers were aware of the remaining cold-chain inadequacies from the PCV introduction, there was insufficient time to mobilize resources to address for these inadequacies prior to rotavirus vaccine introduction.

Our early observations also suggest that the prioritization of activities related to all phases of the new vaccine application, introduction, and routinization process likely contributed to delays in the HSS process. While the period from May to September 2014 expected to witness the development of the HSS application, the IPV application took place and was finalized and submitted, while the HSS application was deferred for a late date. Consequently, critical investments which should strengthen the immunization program and facilitate smoother introductions have been delayed. This is an important topic for further investigation in 2015. It is important that ambitious programmatic goals and plans need to be balanced with effective technical capacity and implementation needs to strengthen immunization systems.

Chapter 6: Cross-Country Analysis and Conclusions

Cross-country analysis

In this section of the report, we analyze and report on the common themes identified across the four Gavi FCE countries. In addition, Table 38 summarizes the findings, organized by the set of original evaluation questions of the Gavi FCE. Additionally, this discussion points readers toward the relevant sections of the report for further detail.

Cross-country finding 1

Gavi's Strategic Goal One (the vaccine goal) is "to accelerate the uptake and use of underused and new vaccines by strengthening country decision-making and introduction." In line with this, support from Gavi over the last two years has contributed to the national introduction of PCV in Mozambique, Uganda, and Zambia; rotavirus vaccine in Zambia; and an MR campaign in Bangladesh. Gavi is also supporting an ongoing HPV vaccine demonstration project in Mozambique. In general, PCV and rotavirus vaccine are being delivered at coverage levels comparable to vaccines already in the system. The MR campaign in Bangladesh reached high coverage and reduced rubella disease susceptibility among the target population, as confirmed by a post-campaign survey. Despite this, wider delivery and monitoring and evaluation of new and routine vaccines are constrained by persistent limitations of immunization delivery systems.

The first of Gavi's four strategic goals is "to accelerate the uptake and use of underused and new vaccines by strengthening country decision-making and introduction."⁴⁵ In line with this goal, Gavi new vaccine support has contributed over the last two years to national introductions of PCV in Mozambique, Uganda and Zambia and rotavirus vaccine in Zambia, with plans underway to introduce PCV in Bangladesh, HPV vaccine nationally in Uganda, rotavirus and measles second dose vaccines in Mozambique, and IPV in all four countries. A demonstration project for HPV vaccine is presently underway in Mozambique and a demonstration project in Bangladesh is scheduled for 2015.

Our ongoing evaluation (p.140, 195, 214) shows that the scale-up of PCV was variable across Mozambique, Uganda and Zambia, with Mozambique demonstrating the most rapid scale-up and Uganda demonstrating the slowest. Our evaluation suggests that the national introduction of rotavirus vaccine in Zambia was improved compared to the earlier PCV introduction; our evaluation indicates several underlying reasons for this improvement. Overall, the findings of our evaluation suggest that these new introductions are generally being delivered at levels comparable to other vaccines already delivered by the routine immunization program, such as pentavalent vaccine, though we note the lower coverage of PCV compared to pentavalent vaccine in Uganda in the more recent time period. In addition to the introduction of new vaccines into the routine EPI program, Gavi support in Bangladesh has contributed to the implementation of a MR campaign targeting 54 million children aged 9 months to 15 years of age. To date this effort is of the largest MR campaigns conducted globally. The campaign achieved high-levels of MR vaccine coverage and resulted in a large reduction in the susceptibility of the target population to rubella. Gavi support for accelerating the introduction of HPV vaccine under the vaccine goal has experienced a more specific set of challenges and is discussed in further detail under Cross-country Finding 2.

Despite the introduction of multiple new and underused vaccines in Gavi FCE countries, in all cases, the ability to fully reach the target population and improve equity is hampered by persistent limitations of the immunization delivery system^{12,33,46} This is best highlighted by the existing geographical and

individual-level inequality in the coverage of existing vaccines (p.52-56, 107-109, 157-160, 208-210). In Bangladesh, those who did not receive the MR vaccine through the campaign were also less likely to have had received other routine EPI vaccines, and MR campaign coverage was lower in those areas with lower routine EPI coverage. Inequality in coverage is a reflection of a variety of delivery system bottlenecks; for example, remaining cold chain deficiencies have contributed to vaccine stock-outs in Zambia (p.219, 224). System deficiencies also prevent timely monitoring and evaluation of the introduction of new vaccines. Administrative data presently suffer from various data quality issues; hence, population-based surveys are needed to understand the true levels of coverage achieved by the introduction of new vaccines. Efforts to address immunization system limitations are critical and are discussed further under cross-country Finding 3, which discusses the HSS stream of support.

Cross-country finding 2

There is a lack of clarity for the primary objective and way to implement HPV vaccine demonstration projects as a mechanism for learning and guiding national HPV vaccine introduction. This is partly driven by insufficient and underutilized technical guidance for countries implementing HPV vaccine demonstration projects. Relatedly, potential pathways from the demonstration project to national introduction are not well articulated. Part of the confusion about the objectives of the demonstration project may stem from a degree of misalignment between the learning objective of the demonstration project and the requirement for countries to have a demonstrated ability to reach 50% of the target cohort in order to qualify for support for national introduction. In other words, in order to meet the requirement of demonstrated ability to deliver HPV vaccine, the demonstration project may not be designed in a way that maximizes the potential learning opportunities for national introduction.

As part of Gavi's Strategic Goal One, Gavi supports the national introduction of HPV vaccine and provides additional support to countries to implement HPV vaccine demonstration projects¹¹ to guide subsequent national introductions. An important cross-country finding centers on the use of HPV vaccine demonstration projects as a mechanism for guiding national HPV vaccine introduction.

In Mozambique, a noted success from our evaluation was the decision by the government to fund additional demonstration sites to broaden the potential learning beyond the Gavi-funded Manhica district (an atypical district from a socioeconomic- and partner-support-perspective). The FCE views this decision as positive because it brought the design of the demonstration project (although partially funded by other sources) more in-line with the stated learning objective of Gavi's HPV vaccine demonstration window of support. However, a subsequent challenge in Mozambique was also faced when the country decided to conduct a census of the target cohort, which was later realized as infeasible to do at national scale, should the country proceed with a national introduction. This decision stemmed partly from insufficient technical guidance and underutilized technical assistance and also reflects the limited understanding that the implementation process of the demonstration project should ideally mirror a potential national introduction.

A different but related challenge was observed in Uganda following approval of the application for national HPV vaccine introduction. In the wake of a reduction in Child Health Day Plus (CDP) funds for districts (CDP was part of the proposed HPV vaccine delivery model), concerns regarding the financial sustainability of the proposed delivery model led to the present decision to modify the delivery model to

¹¹ In discussing this theme, we acknowledge that the demonstration project in Uganda was not Gavi funded; however, there are relevant lessons to be learnt for future Gavi-funded demonstration projects.

one more incorporated with routine EPI. However, this modified delivery model was not one of the primary models tested during the country's earlier demonstration studies. This highlights the need for careful consideration of financial sustainability, including the sustainability of other platforms to be leveraged (such as CDP), when selecting delivery models to test. It also highlights the need to ensure that different delivery models of varying feasibility are tested. Applications for national introduction should be accompanied by an explicit and in-depth costing and sustainability analysis for HPV vaccine, given the different target population and delivery modes that delivery of this vaccine entails. Although this is a stated requirement of past and present HPV vaccine guidelines, our evaluation in Uganda suggests that this requirement was not afforded the necessary level of attention and review that it deserved both at country and Secretariat levels. An assessment of financial sustainability prior to the implementation of HPV demonstration project would help to guide the appropriate delivery model(s) to be tested.

Based on these findings, we conclude that there is some misalignment between the policy that the HPV vaccine demonstration is a learning exercise and the application policy (for national introduction) that requires evidence of demonstrated ability to deliver the vaccine to the target cohort. Specifically, the incentive to reach the demonstrated ability target may lead to demonstration projects that are designed, both in terms of site selection and implementation process, more to reach the target than to maximize the learning experience for national introduction. The incentive to meet the coverage target requirement for national introduction at the cost of a demonstration project designed to maximize learning is noted at both the country and global levels, as reflected in the by key informant statements:

The government wanted to expand to various districts but Gavi was concerned that if they didn't run a good quality demo project it would affect their ability to apply for a national program.
(Global-level KII)

We can't really say definitively for all countries that they adopt the same approach, picking low hanging fruit, choosing a district where they know they will have success, or selecting sites where there is an opportunity to learn... (Global-level KII)

Gavi may wish to revisit the implicit and explicit goals of the HPV vaccine demonstration policy and more clearly align the design and implementation of the HPV program with those goals. Similar situations could be avoided with more explicit policy guidance that the primary objective of demonstration projects is to test and learn about potential delivery models to be used in a national roll out, coupled with consistent and ongoing communication and technical guidance on how to achieve this.

Furthermore, our evaluation found that there appears to be a lack of clarity about the use of demonstration projects and the potential pathways leading to application for national introduction. One option for countries may be to focus on the demonstrated ability criteria in a more favorable site before expanding to more representative sites for broader learning and then applying for support for national introduction. The IRC picked-up on a related suggestion by the Mozambique ICC in its review of Mozambique's application:

The ICC notes that...further demo projects may be needed in other geo/political sections of the country to gain needed experience prior to national application.

The HPV application guidelines do not outline this multi-phase rollout approach as a potential path to national introduction. Further clarification of the guidelines is needed regarding the option of a staged

approach of multiple demonstration sites leading to national introduction and the degree to which this is supported by Gavi.

Cross-country finding 3

Gavi's second strategic goal to "contribute to strengthening the capacity of integrated health systems to deliver immunization" is implemented through its HSS support. All Gavi FCE countries have experienced multiple barriers and slow implementation of HSS support, several of which have been previously documented. Barriers range from difficulties in coordinating across multiple stakeholders and other health system strengthening activities, the complex and diverse range of activities, to implementation delays due to bureaucratic systems for fund disbursement and procurement. This slow progress has direct implications on efforts to increase vaccine coverage and reduce inequalities and additionally affects new vaccine introductions.

Gavi's second strategic goal is to "contribute to strengthening the capacity of integrated health systems to deliver immunization"⁴⁵ which is implemented through its HSS window of support. Health system strengthening activities are critical to support new vaccine introductions and reduce inequalities in vaccine coverage. While countries have faced a range of barriers to implementation for new vaccine introductions, this is especially pronounced for, and has subsequently led to slow progress of, HSS support in all four FCE countries. These barriers occur at multiple stages of the implementation process.

Relative to new vaccine introductions, HSS requires a broader set of stakeholders than the core EPI partners and a reallocation of responsibilities among stakeholders. This can lead to coordination challenges that are reflective of expanded and less developed partnerships.

HSS involves coordinated efforts at the country level, which involves partners even at the proposal stage...Capacity varies widely: staffing, interactions between Gavi and country, coordination between departments (Dept. of Planning, EPI, M&E, and HMIS). There is challenge in bringing these departments together. (Global-level KII)

The array of system strengthening activities can also be exceedingly diverse and may involve complex and lengthy procedures, as in the case of Uganda's procurement system. Many of these are persistent and previously documented challenges; for example, procurement challenges and insufficient time allocated for implementation were noted in the 2008 HSS tracking study³⁷.

HSS activities must also be coordinated with other efforts – both those funded from domestic resources or by other external donors - to strengthen health systems. If delays in the implementation of HSS activities occur, other resources may be utilized in the interim, which necessitates a reprogramming of HSS funds. This reprogramming further contributes to delays in the implementation of HSS.

In comparison to HSS, new vaccine introductions also have higher visibility and political effects given their more easily understood impact on population health and the substantial media attention given to new vaccine launches. New vaccine introductions also involve more prominent champions at both national and global levels.

Involvement of the first lady in advocacy for the vaccine played a big role in getting parliamentarians involved. (KII, Uganda partner)

The combination of less political priority with the more complicated nature of HSS implementation appears to have led to HSS generally being deprioritized relative to new vaccine introductions. For example, in Mozambique the HPV vaccine demonstration project was implemented in 2014 while progress on responding to HSS requirements stalled. This was despite the IRC review that recommended prioritization of HSS over HPV. The FCE notes that this as a relatively early signal in our evaluation work and that this will be followed up in more depth in subsequent FCE reports.

It is critical that HSS is given increased attention moving forward. As we have noted in Mozambique, Uganda, and Zambia, HSS activities such as cold chain expansion are necessary to support subsequent new vaccine introductions. While alternative sources of funding were identified in Mozambique, the delayed implementation in Uganda may still delay the introduction of HPV in 2015. Beyond the implications for new vaccine introduction, HSS is a critical element for addressing persistent system bottlenecks that prevent increases in coverage and potential reductions in health inequalities. Without efforts to extend vaccine coverage, the introduction of new vaccines may exacerbate health inequalities, as those people who are receiving the current schedule of vaccines are more likely to receive new vaccines than those people who are not presently covered by the existing schedule. The priority of HSS implementation has been noted by Gavi and stakeholders. The FCE has yet to see whether the new performance-based HSS design leads to an increase in the priority of HSS implementation. In the four FCE countries we are at an early stage of implementation of the new HSS window. Mozambique is about to begin implementation, Bangladesh and Zambia are in the midst of developing an application, and Uganda is still implementing HSS funds under the previous design.

Cross-country finding 4

Although there is evidence of learning from past experience, planning and management of Gavi support remains an important bottleneck in Mozambique, Uganda, and Zambia. This is a reflection of limited central capacity at the country-level and is exacerbated by concurrent application and implementation of multiple Gavi support streams. We noted several different forms of capacity challenges. These included staff turnover, low numbers of central level staff who are spread too thin, and limited capacity in terms of experience and familiarity with Gavi processes and systems.

As we indicated in the Gavi FCE 2013 process evaluation report of PCV introduction in Mozambique, Uganda and Zambia, these countries experienced a number of planning and implementation challenges introducing PCV. These challenges ranged from upstream problems that included setting realistic planning timelines and getting necessary funds to their ultimate point of use (e.g., health worker training), to post-implementation challenges with supervision and monitoring. During this evaluation period, there is evidence to suggest that countries are learning from these past experiences. In Uganda, UNEPI and partners initiated the preparation phase of the national HPV vaccine introduction early in response to the PCV experience. In Zambia, the EPI program chose to only set a launch date for the rotavirus vaccine introduction after arrival of the VIG in country to avoid multiple instances of rescheduling experienced with the PCV introduction.

However, that there are persistent issues related to the planning and management of Gavi support. For example, in Zambia, submission of the HSS application was postponed until the next application window due to coordination challenges stemming from competing priorities and unfamiliar roles and responsibilities. In Uganda, insufficient attention was paid to the financial sustainability of the proposed delivery model for national HPV vaccine introduction leading to a switch to a model that was not one of

the primary models tested in the demonstration project. In Mozambique, late disbursement of funds to implementers led to rushed implementation of the HPV vaccine demonstration project. In Bangladesh, coordination challenges between a broad set of stakeholders contributed to stall the disbursement and implementation of the first tranche of HSS funds.

These issues are reflective of limited capacity at the central level to plan and manage Gavi support with the national EPI teams comprised of relatively few staff. This is most notable in Zambia, Uganda, and Mozambique. In Bangladesh, human resource capacity at different levels of EPI enabled adaptive responses to operational challenges and political unrest leading to a largely successful MR campaign; however, difficulties in managing the HSS support stream were apparent.

Notably, capacity is limited not just in the preparation and implementation phases of new vaccine introductions, but also applies to the considerable upstream legwork involved in developing applications and in responding to conditions indicated during the approval phase. Our findings highlight the significant work involved in application processes for IPV in all countries, the responses required for MR campaign in Bangladesh, HSS in Zambia, and to develop the responses required following conditional approval of HSS in Mozambique.

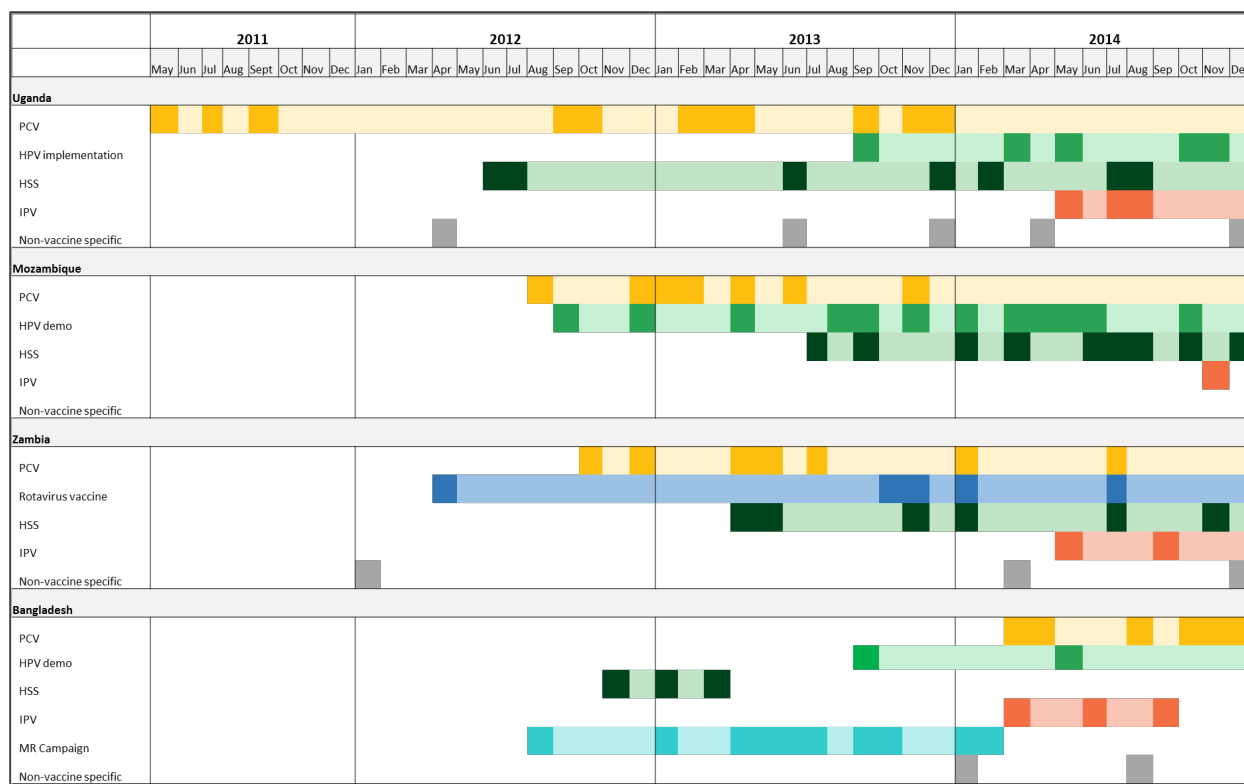
This limited capacity raises questions about the sustainability of Gavi support with capacity constraints exacerbated by the multiple streams of support that countries are applying for and implementing within a short period of time as well as other routine EPI and campaign based demands.

They are also going to do an EPI review and several other activities and couldn't fit everything into the last quarter due to other competing priorities. (Global-level KII)

The polio campaigns which were scheduled for October were moved to November which realistically means they will be conducted in December. The country intends to introduce the [HPV] vaccine in 2015 however there are so many competing priorities. We have to keep in mind that these teams are the same. (Uganda partner KII)

Figure 92 provides a graphical representation of activities by country and support stream, highlights the extent of Gavi-supported activities being undertaken in the four Gavi FCE countries. Of particular note is that during the evaluation period, all four countries commenced with applications for IPV introduction, although IPV was not part of formal country plans at the time countries decided to apply for support. Decisions to implement previously unplanned support streams may be well-justified and reflect changing global and country health priorities. However, the incorporation of these new support streams must be accompanied with a re-examination of planning and timelines for other EPI priorities. In the Mozambique section of the report (p.132), we highlight that, in particular during the 2015 period for Mozambique, the introduction of rotavirus, measles-second dose and IPV are planned alongside the ongoing implementation of a multidistrict HPV vaccine demonstration project and HSS support. This workload is likely to be unmanageable given the challenges the country faced in 2014 with implementing the HPV vaccine demonstration project while applying for IPV and responding to clarifications for HSS.

Figure 92: Visualization of activities by country and support stream



This figure is a graphical representation of ongoing Gavi-relevant funding streams in each of the FCE countries; it corresponds to each of the country timelines presented in Figure 11, Figure 29, Figure 51, and Figure 70. The color of bands is coded to the funding stream. Dark cells indicate that a significant event occurred in that month, while lighter cells indicate that work in this stream is ongoing.

Cross-country finding 5

Although there is evidence to suggest that country-level partnerships consisting of Expanded Program on Immunization (EPI) programs, World Health Organization (WHO), UN Children’s Fund (UNICEF), and others are growing stronger and expanding to include a greater range of stakeholders, the observed partnerships do not always have the right people, in the right numbers, in the right structures, and with the right motivation to deal with the workload required to apply, plan for, and implement multiple Gavi support streams. Our findings suggest that the Gavi Secretariat, in particular, Senior Country Managers (SCMs), are not necessarily viewed as part of the partnership. A re-examination of SCM engagement with country stakeholders, including consideration of greater in-country presence may improve the partnership structure, and thus outcomes.

Given the limited central capacity in most of the FCE countries to manage the multiple streams of Gavi support in addition to routine EPI activities, the roles of country-level partners to support these processes are critical. The FCE partnership framework (see Annex 11) posits that the composition and structure of a working partnership will have important consequences on whether individuals in the partnership can fulfill their roles to the best of their ability, and whether the partnership can perform as a whole, ultimately improving effectiveness, efficiency, and country ownership of Gavi-related processes. We found that few countries referred to the set of country-level stakeholders (including the government and country-level partners) working together on immunization issues as a “partnership;”

however, when asked to provide their own definition of partnership, respondents frequently provided a working definition that was very similar to what we had outlined in the partnership framework document.

Partnership is a group of stakeholders working together to achieve a common goal. In the context of immunization the goal of the partnership is to pull resources together and make sure that every child in Uganda is fully immunized. (KII, Uganda)

Involvement of other stakeholders working together with UNEPI to implement activities effectively. All stakeholders involved bring different things to the table like personnel, transport, Technical Assistance etc. (KII, Uganda)

Context influences structure

Country-level conceptions of who makes up a partnership differ from how Gavi's partnership model is framed in Gavi documentation.^{45, 47} The FCE findings suggest that there is no single "partnership" surrounding Gavi support in a given country, but rather a shifting set of partners based on the stream or activity. A core group of members – mainly from MOH EPI programs and WHO and UNICEF country offices – participate actively in Gavi-related activities and routine immunization activities at the national level. Traditional EPI partners such as WHO and UNICEF have provided technical assistance such as orientation and training on the new HSS window of support and IPV applications. Beyond this, the composition of a given partnership depends on the nature of the stream and its activities, as well as requirements from Gavi. For example, HPV partnerships tended to include a broader range of stakeholders than other new vaccines, including country-level technical assistance. Across countries, the HSS stream was perceived to involve a shift in the composition of partners and their roles, with a common example being the expanded role and responsibility of the planning department within the MOH/MCDMCH.

An important finding from our partnership analysis in Uganda is the suggestion that the Gavi Secretariat and regional- and headquarter-levels of partner organizations are not necessarily viewed as part of the partnership. The Gavi Secretariat was not named unless prompted during partnership interviews about the HPV vaccine application process in Uganda. This is potentially consistent with the scope of their official responsibility: to review the application after submission. However, the fact that neither they, nor partners from regional or headquarters offices, were named, suggests that they were not the first source for information or technical assistance sought by country-based stakeholders in that case example and suggests that there is limited visibility at the country level for stakeholders outside of the country. Our evaluation also suggests that this goes beyond the specific case of HPV in Uganda, particularly with reference to the Senior Country Managers' role. SCMs' capacity for deeper, substantive engagement and relationship-building with country stakeholders was limited by their out-of-country location and responsibilities for grants management across multiple countries.

...the amount of time that can be dedicated to countries is based on crisis management more than regular building of partnership work. (KII, Global)

Notwithstanding the Secretariat's stated goal of increasing the number of SCMs, these findings suggest a need for re-examining Secretariat policies around SCM engagement with country, including consideration of greater in-country presence.

Trust was a theme that emerged across countries and in global KII and was considered by many to be a necessary condition of a functioning partnership.

Trust is a very important aspect in a partnership. There cannot be one without the other. (KII, Uganda)

The existence and strength of trust between partners seemed related to a number of factors, including how long partners have worked together, whether partners were national or international, and the overall level of participation in the process. There is evidence that the level of trust within country-level partnerships is growing stronger, in part because of ongoing, consistent working relationships and multiple opportunities to learn from past experiences, as was the case for HPV in Uganda. In Bangladesh, partners' ability to pull together and deal with a potential crisis was partly a function of their established relationships and their collective experience with immunization. A poignant example, noted by a global level key informant, is the way that strong relations between MOHFW and the media ensured that "responsible messaging" around a small number of AEFIs during the MR campaign maintained public confidence in the vaccine and in EPI.

In Uganda, respondents reported higher levels of trust for local partners compared to international ones, and for established partners versus new ones. These comments were particularly made in reference to technical assistance provided by organizations beyond established partners; while these individuals were perceived to be hard-working and effective, they did not benefit from the same level of trust as existing partners.

Regarding competence, no major problems with the current stakeholders. For partners like [X] who are new players in the immunization field they have been asked to work closely with UNICEF. (KII, Uganda)

Efforts should be made to identify in-country partners whenever possible. Technical assistance activities should aim to ultimately strengthen the capacity and availability of these in-country partners. In Mozambique, available technical assistance from an international partner was not readily leveraged, and the delay in engaging with the partner was perceived to be an issue of trust. Issues of trust are important as Gavi continues to explore how to most effectively provide technical assistance above and beyond what WHO and UNICEF country offices provide.

Issues with trust are exacerbated by frequent turnover in Gavi, partner organizations, and ministries of health. One global-level key informant reported investing considerable time in building trust with country governments, only to have it collapse when she was abruptly re-assigned to a new position, highlighting the fact that relationships and trust occur between individuals, not organizations. Turnover was a contextual factor that had an important influence on the structure and performance of immunization partnerships. While there were positive stories that emerged from staff transitions, as was the case with the new EPI and MOH leadership in Uganda, there were several instances where changes in staff may have delayed processes, or made it more difficult for technical assistance to be delivered. Strengthening relationships between organizations and increasing the overall resilience of partnership networks can help mitigate the effects of turnover.

Structure influences practices and performance

While the structure of partnerships varied across streams and countries, patterns are beginning to emerge in terms of how structure influences the ability of partners to fulfill their roles and the overall performance of the partnership. Some partnerships appeared more resilient to unexpected challenges than others. As noted above, the Bangladesh partnership for the MR campaign was able to adapt to political upheaval; this was partly attributed to the partnership's inclusion of health workers and other subnational actors, resulting in a decentralized and adaptive partnership.⁴⁸ In Uganda, the HPV partnership was relatively decentralized, but also well-connected and dense, indicating that members shared responsibilities, information, and authority relatively equally, and also that members had strong, trusting relationships between them. This partnership structure was generally effective in completing the application in a timely manner, although we observed an inadequate assessment of the financial sustainability of the national HPV vaccine delivery model, which may reflect that this partnership was not as effective as it could have been. A broad range of stakeholders who were familiar with their roles and responsibilities were also instrumental in the smoother launch of rotavirus vaccine compared to past introductions in Zambia.

Other partnership structures were not suited to their intended function. Across countries, the shift in authority to departments of planning seemed to be one root cause of HSS implementation delays. In Bangladesh, the department's concerns around political transition delayed the implementation of HSS and yet a more-decentralized partnership may have been able to share responsibility and decision-making authority to move HSS implementation along. In Zambia, the department of planning took time to adjust to their new role, slowing the process. It should be noted that slower processes resulting from the addition of new partners is not necessarily bad, nor are slower and more deliberative processes stemming from increased shifting in responsibility to ministries of health. Both scenarios are more likely to achieve the goals of evidence-based decision-making, financial sustainability, and alignment and country ownership in the long term. Health policy partnerships tend to take years of membership building and process refinement before they begin to attain goals,⁴⁹ and as country-level partnerships continue to mature, appropriateness of representation should trump speed. Ongoing analysis will aim to identify this balance in countries.

In parallel to HSS partnerships, some other partnerships seemed to suffer from too little diversity and over-centralization. Smaller partnerships for the IPV application were noted in Uganda, Mozambique, and Zambia, leading to faster application processes but less country ownership. While IPV may not necessitate as broad and diverse a group of stakeholders as the more multisectoral/departmental HPV vaccine or HSS processes, country-level respondents seemed to perceive the IPV partnerships as being inherently different from other decision-making processes. Ugandan respondents considered the IPV application to occur outside of normal application processes and procedures, involving fewer partners, and resulting from a "global push." Even country-level staff of partner organizations perceived this political priority and related pressure:

Some of these resolutions are made in the World Health Assembly [i.e., by Ministers of Health from all countries], so us, (country-level partner offices) have to implement these resolutions. So the pressure comes from the global level. (KII, Uganda)

In Zambia the IPV application was developed by a six-member team (Department of Planning and Information, Child Health Unit, WHO, UNICEF) and was not discussed in EPI Technical Working Group meetings. In Mozambique the application was also written by the National Immunization Program,

UNICEF, and WHO – a smaller-than-usual group. The smaller size of partnerships may have accelerated the time it took to prepare the application, as was suggested in Uganda and Zambia, but may also have consequences for country ownership and sustainability of IPV programs:

Yes, the HPV application partnership facilitated country ownership of the process unlike IPV application process. (KII, Uganda)

Global level KIIs indicated that IPV had stronger partner engagement from global partners due to the political commitment around the Polio Endgame Strategic Plan, heightened advocacy and messaging, and greater financial resources to get countries ready for introduction. At the global level, the IPV partnership benefitted from the common commitment to IPV from all partners, more so than other new vaccines:

The difference is that [new vaccine introduction] is often seen as a Gavi goal, a Gavi objective. Here, we are seeing it as a joint goal. (KII, Global)

It is interesting to note that while the global-level IPV partnership was perceived to be larger, more motivated, and more effective than for other new vaccine partnerships, the country-level partnerships seemed to have simultaneously suffered from the shift in the locus of authority. This issue ultimately stems from the Gavi policy decision to streamline the IPV application. Tracking the consequences of the IPV application policy on IPV partnerships and thus on the achievement of NVS objectives will remain an important focus of the FCE in the coming year.

Partner practices and partnership performance influence partnership's added-value

The issue of lack of clarity around roles and responsibilities also limited the overall effectiveness of the partnerships at country-level. The same is likely true for the global and transnational partnerships; this will be explored in greater depth in the coming year. In Uganda, few country respondents were aware of the Gavi Business Plan and some of the country-level partner roles and responsibilities that were decided at the global level. A key informant at the global level considered the awareness of the business plan to be increasing in countries, and noted that additional processes have been put in place to coordinate technical assistance between partners and across levels, but in-country respondents were unable to articulate whether or how country governments knew what to expect from country-level partners. Among country-level partners, roles and responsibilities were often determined on an ad-hoc basis, or occasionally assigned by EPI or MOH management committees. In Mozambique, partner roles for the HPV vaccine demonstration project were not clarified until the SCM intervened; prior to that, partners could not agree on who was responsible for what. While a “true” partnership may not have a “leader,” the intentional management and administration of a partnership can strengthen performance, particularly for less mature and/or mandated partnerships:⁴⁹

One thing about technical assistance –assistance is very good as long as you can manage it. In many of these countries if there are too many cooks in the kitchen it won't work. It works well as long as there is a counterpart in the country to manage the TA that is provided. The ministry in general is not too much staffed – always high level of vacancies. You need to have feet on the ground. (Global KII)

A key informant reported that the Ugandan Ministry of Health is exploring a new initiative to better manage partnerships across the range of health programs and development assistance. Gavi should support such country efforts.

Cross-country finding 6

Communication between the Gavi Secretariat, country partners, and government, particularly around Gavi Secretariat procedures and guidelines, remains an ongoing barrier to progress. There is a need for a set of more formalized procedures and guidelines and increased communication around, for example, changes in plans and roles from the approved application, and around fund disbursement.

In the 2013 report we identified that communication, particularly around the disbursement procedures and timing of the VIGs, was a notable challenge. Our findings for this evaluation period also highlight that communication and implementation of Gavi Secretariat policies and procedures are an ongoing challenge. This year's data are not able to discern the exact root cause of the problem, but suggest that it has something to do with the processes in place to disseminate new and changed policies and procedures along the communication chain. This is related to, and possibly the cause of, the partnership finding that country-level partnerships had few consistent linkages to global partners. Unclear or inappropriate procedures for the exchange and dissemination of policies, information, and technical assistance are limiting the ability of said inputs to achieve their intended impact.

Country-level data highlight an acute lack of familiarity with Gavi policies among country-level respondents. In this respect the finding is largely not an evaluation of Gavi policies, but rather the processes around their dissemination and implementation.

In Mozambique, implementation of the HPV vaccine demonstration was delayed in part due to lack of clarity around expectations for roles and responsibilities. Whether these expectations are encoded in Gavi policy was unclear to respondents, but resolving the question was further delayed by turnover at the Gavi Secretariat and NIP. In Uganda, we identified different expectations within and across MOH, country-level partners, and Gavi Secretariat around the timing of the VIG disbursement for HPV vaccine as well as ongoing misunderstanding of the VIG disbursement procedure. With the new HSS window of support, ensuring understanding of the HSS guidelines is important. For example, our evaluation findings highlight that the MOH in Bangladesh was not familiar with the FMA requirements to submit an external audit assessment, which led to delay in approval of HSS reprogramming. Yet another example of unclear policies is that, following the transfer of HSS procurement responsibility outside the government of Uganda, the government reported that they perceived the need to update the MOU between themselves and Gavi. Global-level key informants stated that Gavi policy did not require an updated MOU. Either way, the perceived need for a revised MOU further delayed the HSS implementation process. Gavi could address similar issues in the future through two mechanisms: clearer procedures outlining how information and policies are disseminated from the Secretariat to countries; and stronger efforts to address alignment with country-level administrative requirements. Broader issues of communication and Gavi policy implementation could be addressed, for example, by more formalized, written procedures that cover changes in roles and plans from the approved proposal as well as a written template for disbursement and timing of cash support for vaccine introductions and demonstration projects as was recommended in the Uganda and Mozambique sections of this report. This could also be combined with increased technical assistance, e.g., further training on the new HSS window of support, and enhanced regular communication between the Gavi Secretariat and country

programs and partners. Our global-level key informants mentioned regular (weekly- or bi-weekly) calls between Secretariat program managers and SCMs, and regional and headquarter level Vaccine Alliance partners. One key informant mentioned regular weekly calls with country-level WHO offices. However, direct communication between the Gavi Secretariat and EPI programs and country-level partners appears to be more ad-hoc and primarily limited to email and in-country visits at this time. Another key informant mentioned that the country support team is currently working to establish regular calls with EPI managers, which we also recommend. As noted also in the partnership section, the issue of staff transition and how this can be managed is critical. Global-level key informants indicated a lack of effective management by the Secretariat of role transitions for the SCM in Mozambique and Zambia negatively impacted countries. Strategies to mitigate the issue of staff turnover at both country levels and the Secretariat are required to minimize the oft-resulting effect of delayed implementation of Gavi support. Questions around policy dissemination and trans-national communication chains will be explored in greater depth during 2015.

Evaluation questions and corresponding findings

In this section, we return to the original evaluation questions contained in the RFP for the Gavi Full Country Evaluation. Table 38 outlines the evaluation questions relevant to the evaluation work thus far, and findings from this evaluation period that address the research questions.

Table 38: Evaluation questions and findings

Research questions	Findings from this evaluation period that address the research question
Relevance	
1. To what extent is the design of Gavi support and its implementation aligned with Gavi priorities and principles?	<p>Gavi support is well-aligned with the priority of <u>accelerating uptake of new vaccines</u>; in the last two years Gavi support has contributed to the introduction of PCV in three of the FCE countries, rotavirus vaccine in one country, and supported the implementation of an MR campaign in one country (p. 59). In addition, Zambia (not funded by Gavi), Mozambique (one of three districts funded by Gavi; p. 111), and Bangladesh (p. 93) are conducting or plan to conduct HPV vaccine demonstration projects with an eye toward national introduction of HPV vaccine. All countries are planning future new vaccine introductions in 2015 and 2016 with support from Gavi.</p> <p>Although the design of Gavi HSS support is well aligned with <u>strengthening capacity of immunization delivery systems</u>, we have noted slow progress in its implementation at country level that reflects, in part, capacity limitations at the central level (p. 259).</p> <p>In Uganda, we note challenges with the financial <u>sustainability</u> of the HPV vaccine introduction which reflect an insufficient assessment of the cost of the proposed delivery model (p. 162). We also note that constrained capacity at the central level and in the target countries is likely a significant barrier to ensuring sustainability of the implementation of Gavi supported programs (p. 259). Government of Uganda resources for immunization have expanded in line with increases in the overall resource envelope for immunization, however, a large fraction of the immunization resource envelope are contributed by external donors (p.152). This is also the case in Mozambique (p.101).</p> <p>We have also noted some misalignment of Gavi support with respect to <u>country budget process and ownership</u>. For example, in Uganda auditing reports were</p>

Research questions	Findings from this evaluation period that address the research question
	<p>not aligned with the country's financial system and there was a shift from the country's procurement process to procurement through partners (p. 175).</p> <p>We noted both positive and negative elements of the <u>partnership</u> amongst countries and partners across multiple levels (p. 261).</p>
<p>2. To what extent is the design of Gavi support and its implementation at the country level relevant to the country's needs and aligned with the country's priorities and systems?</p>	<p>The introduction of rotavirus and PCV was well aligned with countries' priorities to reduce child mortality, with pneumonia and diarrhea being major causes of death in those FCE countries.</p> <p>Although the MR campaign was not included in the country's cMYP, routine MR vaccine was included, and was aligned with stated health priorities and surveillance data (p. 59).</p> <p>Demonstration projects in Mozambique and Uganda's planned nationwide HPV vaccine introduction, were well aligned with country priorities around reduction of HPV infection and cervical cancer.</p> <p>Preliminary evidence suggests that decisions by FCE countries to introduce IPV appear to be driven to a great extent by top-down push, in line with the Global Polio Eradication Strategic Plan, through incentives such as the co-financing waiver (p. 95, 143, 196, 249). The pace of application and introduction planning appears to be faster than other NUVI, due in part to increased financial resources and technical assistance. Cross-cutting effects of the IPV support stream on other NUVI and HSS will be investigated in greater depth moving forward.</p> <p>The slow implementation progress of HSS relative to the pace of NUVI has limited the potential to increase vaccine coverage in these countries to further contribute to improving health outcomes and reducing health inequality (p. 258).</p>
<p>3. How do Gavi's process, products, and resources work at the country level to influence immunization-related outcomes? Are they improving over time? What are the intended and unintended consequences?</p>	<p>All findings for this evaluation period relate to the overall research question and we do not attempt to summarize them here. Unintended consequences are discussed under Impact, question 6.</p>
Effectiveness	
<p>1. In the four target countries, how do achieved outputs at each phase align with goals and objectives outlined in the 2011-2015 Gavi Alliance Strategy and Business Plan?</p>	<p>The introduction of PCV, rotavirus vaccine, and the MR campaign are directly aligned with Strategic Goal 1, accelerating the uptake and use of new and underused vaccines. The applications and upcoming implementation of other vaccines such as HPV vaccine and IPV are also directly aligned with this goal. The implementation (including reprogramming) of HSS, although delayed in Bangladesh and Uganda, are directly aligned with Strategic Goal 2 of strengthening capacity of integrated health systems to deliver immunization.</p>

Research questions	Findings from this evaluation period that address the research question
	<p>We have yet not identified specific outputs that have contributed to improving the sustainability of national financing for immunization during this evaluation period.</p>
<p>2. How do achieved outputs at each phase contribute to meeting the specific objectives for the corresponding window of support (cash-based support versus new vaccine support)?</p>	<p>For new vaccine support evaluated in the FCE countries:</p> <ul style="list-style-type: none"> • Our assumption is that the introduction of new vaccines with Gavi support have <u>accelerated uptake and use of new and underused vaccines</u>. However, it is difficult to quantify by how much this has accelerated introduction. • There was indication of <u>evidence-based decision making</u> with regards to decisions to introduce these vaccines, with all countries indicating high burden of the corresponding disease. For polio, where disease burden is low, the decision to apply for Gavi support to introduce IPV is in line with the Global Polio Endgame Initiative. • There is evidence from Uganda that the chosen delivery model for HPV vaccine national introduction is not financially sustainable which prompted a shift to an alternative delivery model (p. 162), a positive signal that the country is thinking toward <u>sustainability of national financing for immunization</u>, even though the issue arose late in the process. • Relatedly, there appear to be some misalignment with the national planning and budgetary process of HPV vaccine national introduction as these issues of financial sustainability were identified only after the application was submitted and approved. <p>For cash-based support:</p> <ul style="list-style-type: none"> • As noted earlier there have been challenges and delays in the implementation of HSS in all Gavi FCE countries (p. 258). • As a result, the Gavi FCE is still collecting information on the extent to which the HSS outputs are contributing to <u>resolving the major constraints to delivering immunization, increasing equity and strengthening civil society engagement</u>.
<p>3. To what extent does the Gavi funding mechanism at the country level (e.g., HSS, ISS, NVS) and its implementation contribute to attainment of the country's stated goals (National Health Strategy/cMYP)?</p>	<p>Although the introduction of new vaccines will contribute to the attainment of child mortality reduction and disease-specific goals, we have not yet assessed the extent to which this has occurred nor quantified the contribution of the Gavi funding mechanisms. Similarly, we have yet not quantified the contribution of cash-based support to the attainment of country's stated goals.</p>
<p>4. At both the global and country level, how do the Gavi Partnership inputs (from different partners) contribute to results achieved at the country level?</p>	<p>During the evaluation period we identified a number of instances of stronger partnerships around Gavi support, including:</p> <ul style="list-style-type: none"> • In Zambia we noted a stronger partnership of EPI stakeholders that led to a smoother introduction of rotavirus vaccine compared to previous introductions (p. 220). • In Uganda and Mozambique, we witnessed broadening partnerships for the HPV vaccine support stream (p. 111, 162). • In Bangladesh, we noted strong partnerships contributed to the implementation of the MR campaign, despite political unrest (p. 69).

Research questions	Findings from this evaluation period that address the research question
	<p>Partnerships, however, remain limited in the context of multiple new vaccines and system strengthening activities in addition to regular EPI activities, in particular:</p> <ul style="list-style-type: none"> • We noted more tentative cross-border partnerships, i.e. between country, regional and global levels (p. 261). • Relatedly, few country-level partners could clearly articulate the Gavi Business Plan and partner roles and responsibilities (p. 265). • Partnerships were notably affected by turnover of individuals (p. 266). <p>These aspects of partnership are an important ongoing area of the Gavi FCE work.</p>
<p>5. To what extent does the Gavi funding mechanism at country level (e.g., HSS, ISS, NVS, and including TA) and its implementation reflect country-level ownership, alignment, harmonization, managing for results, and mutual accountability?</p>	<p>We noted some challenges in the implementation of Gavi support with respect to these dimensions, including:</p> <ul style="list-style-type: none"> • The shift in the procurement process in Uganda from the government system to an alternative partner means less country ownership and less alignment with country systems (p. 175) • In Uganda we also noted a misalignment of requests by Gavi for financial reports with the country financial system which uses a different financial year (p. 178) <p>We also noted positive aspects of country ownership. For example, the shift in roles and responsibilities in Mozambique for the HPV vaccine demonstration was such that the MOH was the lead entity and funding recipient, increasing country ownership and alignment with subsequent national HPV vaccine introduction (p. 111).</p>
Impact	
<p>1. What is the immunological evidence of effective vaccination?</p>	<p>The MR campaign in Bangladesh had an effect in reducing susceptibility to rubella as measured by rubella antibodies by increasing effective immunization coverage of the MR vaccine (p. 69).</p> <p>An assessment of the immunological evidence of effect vaccination is part of forthcoming surveys in 2015 as part of the FCE.</p>
<p>2. To what extent have reductions in morbidity and mortality of vaccine preventable diseases occurred? To what extent has Gavi contributed to such reductions?</p>	<p>All countries have experienced declines in the mortality of vaccine preventable diseases; the reduction in morbidity and mortality related to the introduction of PCV in Mozambique is being assessed as part of an ongoing vaccine effectiveness that is part of the FCE.</p>
<p>3. To what extent have reductions in child and adult mortality occurred in Gavi supported countries? To what extent has the Gavi Alliance contributed to such reductions?</p>	<p>All countries have experienced reductions in child mortality; the analysis of the contribution of new vaccine introductions and HSS to child mortality using small area estimates and surveys is a part of future FCE work.</p>

Research questions	Findings from this evaluation period that address the research question
4. To what extent has Gavi support contributed to social and financial risk protection for populations in countries supported by Gavi?	A cost-of-illness study as part of the vaccine effectiveness study in Mozambique is part of future FCE work.
5. To what extent does Gavi support contribute to improved equity between and within countries, including, but not limited to, gender equity and equity between the poor and the non-poor?	<p>Overall, equity in terms of the ratio of DPT3 coverage in the richest quintile vs poorest quintile (as measured by household wealth) has improved in all FCE countries, but inequities remain (p. 51, 107, 157, and 207). DPT3 coverage is generally equitable by gender with notable improvements in Bangladesh. Geographic inequity in terms of DPT3 coverage and full vaccination at the district and upazila levels improved markedly in Bangladesh. Geographical inequity between 2000 and 2013 has remained more or less than same in Mozambique, Uganda and Zambia.</p> <p>The analysis of the contribution of Gavi support to reduction in inequality is a part of future FCE work.</p>
6. Across all phases (decision to apply, application, preparation, implementation) what positive or negative unintended consequences have occurred as a result of Gavi support?	<p>We identified a range of positive and negative consequences as a result of Gavi support, including:</p> <ul style="list-style-type: none"> • Gavi support acting as catalyst for other funding in Uganda and Zambia (p. 201, 252). • New vaccine introductions helping identify system bottlenecks in Mozambique (p. 145). • New vaccine introductions serving as a catalyst for stronger partnerships in Uganda (p. 145, 201). • Prioritization of new vaccine support, such as IPV, contributing to delays in the HSS application process in Zambia (p. 244) and the HSS implementation process in Mozambique (p. 129). • Multiple vaccine introductions in a short period of time in Zambia contributing to accelerated introduction, affecting the ability of the EPI program to learn from and address challenges identified in previous introductions (p. 252). • Transition of procurement to alternative partner leading to further delays and misalignment in Uganda (p. 201). • A range of positive and negative effects of the MR campaign on routine EPI (p. 77).
Efficiency	
1. To what extent is Gavi support cost-effective?	The analysis of the costs and lives saved related to Gavi support are part of future FCE work.
2. To what extent have the following occurred in a timely manner: a) approval of cash support from Gavi, b) disbursement of money from Gavi to countries, c) utilization of funds and implementation of activities	<p>In the implementation of cash-based support, we noted a range of challenges related to the timely approval, disbursement and use of cash-based support:</p> <ul style="list-style-type: none"> • There were delayed development of responses, M&E frameworks, and operational plans in Mozambique (p. 129) • There were delays (Mozambique, p. 129) or suspensions of support (Uganda, p. 175) that required reprogramming of funds. This took time, leading to subsequent delays in utilization of funds.

Research questions	Findings from this evaluation period that address the research question
<p>by countries, and d) achievement of objectives?</p>	<ul style="list-style-type: none"> • There was slow utilization of funds due to lengthy and bureaucratic procedures related to, for example, procurement in Bangladesh (p. 86) and Uganda (p. 175). • There were challenges in the approval of MR campaign vaccine introduction grant for implementation in Bangladesh (p. 59). • There was late onward disbursement by the MOH of HPV vaccine demonstration VIG funds to implementing partners in Mozambique (p. 111). Notably, the disbursement of HPV vaccine demonstration VIG funds from Gavi to the MOH occurred well ahead of the launch date in contrast to the previous experience from PCV. • There was uncertainty about the timing and procedure for the HPV vaccine introduction grant arrival in Uganda (p. 162). <p>For other aspects of approval, disbursement and use of cash-based support in the Gavi FCE countries we did not identify significant challenges.</p>
<p>3. To what extent have the following occurred in a timely manner: a) approval of new and underused vaccine support from Gavi to countries, b) shipment and delivery of Gavi-supported vaccines, c) utilization of supply and implementation of immunization programs, and d) achievement of objectives?</p>	<p>Overall vaccine support from Gavi and the related downstream processes generally occurred in a timely manner, although some challenges and responses to them were noted in particular in this evaluation period:</p> <ul style="list-style-type: none"> • In Bangladesh, the PCV introduction was postponed due to challenges with global vaccine supply (p.93). • In the MR campaign in Bangladesh, political unrest and other factors such as microplanning and registration contributed to vaccine stockouts (p. 80). • Challenges in the supply of PCV and rotavirus vaccine to facilities in Zambia as evidenced by stock-outs were due to ongoing cold-chain deficiencies and inaccurate target population estimates (p. 213, 220). • In Uganda, while there were problems with the supply and distribution of vaccine that accompanied the transition from UNEPI to NMS, these issues were resolved to allow the rollout of PCV to occur (p. 187).
Sustainability	
<p>1. Considering the people, processes and structures that Gavi has invested in, what elements are likely to continue after direct support ends and what is the level of commitment by government to provide ongoing support?</p>	<ul style="list-style-type: none"> • Our evaluation noted the sustainability aspects of the national HPV vaccine introduction in Uganda (p. 162). This highlights the importance of considerations of sustainability when applying and planning for Gavi new vaccine support, given that this support does not include resources for funding routine delivery. Government of Uganda resources for immunization have expanded in line with increases in the overall resource envelope for immunization. However, a large fraction of the immunization resource envelope are contributed by external donors (p. 151). This is also the case in Mozambique (p. 103).
Program implementation and context	
<p>1. What are the most important factors that affect program implementation, effectiveness, efficiency, and sustainability?</p>	<p>The most important factors affecting program implementation we noted in this evaluation period were:</p> <ul style="list-style-type: none"> • Central capacity for planning and managing multiple Gavi support streams (p. 259) • Competing priorities related to other Gavi support streams as well as routine EPI and campaign demands (p. 259) • Evidence of stronger partnership but these remain insufficient for the multiple streams of support being implemented (p.261)

Research questions	Findings from this evaluation period that address the research question
	<ul style="list-style-type: none"> • Communication between Gavi and countries, particularly around Gavi procedures (p. 266)
<p>2. To what extent has Gavi support been responsive to changes in context? In other words, to what extent have Gavi stakeholders used an adaptive management approach to learn from experience where appropriate?</p>	<p>We identified a number of areas which represented adaptive management from past experience, these include:</p> <ul style="list-style-type: none"> • Initiation of early planning for the HPV vaccine national introduction in Uganda (p. 162) • Incorporation of informal lessons, e.g. setting launch date only after arrival VIG, in Zambia (p. 220) • Earlier disbursement of the HPV vaccine demonstration VIG from Gavi to MOH in Mozambique (p. 111) • A range of instances of adaptive management from the implementation of the MR campaign in Bangladesh in response to, for example, political conflict (p. 69)
<p>3. To what extent do the main stakeholders at the country level contribute to the planning, implementation, monitoring, and evaluation of Gavi support? To what extent are their activities coherent and complementary?</p>	<p>During the evaluation period we identified a number of instances of stronger partnerships around Gavi support, including:</p> <ul style="list-style-type: none"> • In Zambia we noted a stronger partnership of EPI stakeholders that led to a smoother introduction of rotavirus vaccine compared to previous introductions (p. 220) • In Uganda and Mozambique, we witnessed broadening partnerships for the HPV vaccine support stream (p. 111, 162) • In Bangladesh, we noted strong partnerships that contributed to the implementation of the MR campaign despite political unrest (p. 69) <p>Partnerships, however, remain limited in the context of multiple new vaccines and system strengthening activities in addition to regular EPI activities, in particular:</p> <ul style="list-style-type: none"> • We noted more tentative cross-border partnership (i.e., between country, regional and global levels) that reflected less trust of international partners (p. 261). • Relatedly, few country-level partners could clearly articulate the Gavi Business Plan and partner roles and responsibilities (p. 261). • Partnerships were notably affected by turnover of individuals (p. 261). <p>These aspects of partnership are an important ongoing area of the Gavi FCE work.</p>

Strengths and limitations

As with any evaluation study, there are both strengths and weaknesses of the evaluation methods and of the Gavi FCE study and reported findings.

Mixed-method approach

The Gavi FCE uses a mixed-method approach to understand the full results chain from inputs to impact. In the 2013 report, we carried out process evaluation of PCV in Mozambique, Uganda, and Zambia, which was based on qualitative methods. In the current report, we combined an array of quantitative methods that complemented the process evaluation. These include analysis of secondary data to generate estimates of vaccine coverage and child mortality at subnational levels, analysis of HMIS to

understand the rollout of new vaccine introductions, and estimates of national-level expenditure data on immunization. In Zambia, we incorporated results from a health facility survey of a sample of representative facilities, which included continuous measurement of cold-chain temperatures. In Bangladesh, we incorporated pre-and-post-campaign surveys with campaign session observation, exit interviews and health worker surveys with process evaluation methods.

This mixed-method approach allows for triangulation of findings from different sources, which increases the robustness of findings and allow for a more in-depth understanding. For example, in Zambia our analysis of PCV and rotavirus vaccine stock-outs, there was convergence of findings from the health facility and KIIs regarding the contribution of persistent cold-chain deficiencies to vaccine stock-outs. We have also used findings from one component to inform data collection in another. For example, we identified training and the presence of PCV fridge stickers as an issue in the process evaluation and incorporated these into the health facility survey to measure this more broadly.

Relatedly, a limitation of this year's report is that we have not fully implemented all evaluation components across countries. Health facility surveys are in progress or planned for early 2015 in Bangladesh, Mozambique and Uganda, while household surveys are in progress or planned for the first quarter of 2015 in Zambia, Uganda, and Mozambique. The vaccine effectiveness studies of PCV in Mozambique and Bangladesh are also ongoing. These additional components will provide a richer understanding of the implementation of Gavi support and immunization system performance.

Evaluation across multiple streams, phases and perspectives of Gavi support

An important feature of the Gavi FCE design compared to past evaluations of Gavi support is the concurrent evaluation of all relevant streams of Gavi support in a country. As highlighted by the findings of this report, this allows us to understand the interactions between these streams of support. Examples of this include the implications of delayed HSS support on future new vaccine introductions, as well as the competing priorities that arise from multiple support streams.

The Gavi FCE covers all phases of Gavi support from decisions to apply, application and approval, preparation, and implementation. This broader evaluation complements the post-introduction evaluations (PIEs) conducted for new vaccine introductions tend to focus on the preparation and implementation phases. Our findings from this year's report highlight the importance of covering all phases, particularly as bottlenecks earlier on in the process have notable downstream consequence. For example, the insufficient attention paid to financial sustainability of the proposed delivery model for HPV vaccine has sizeable implications on the preparation for national HPV vaccine introduction in Uganda. Our evaluation also complements the PIE by extending beyond the usual six- to twelve-month time period post-introduction, as shown by our ongoing analysis of the PCV introductions reported on last year in Mozambique, Uganda, and Zambia.

The FCE leverages and complements other evaluation activities conducted as part of Gavi support. For example, the required evaluation of the HPV vaccine demonstration project in Mozambique will focus on the implementation of the demonstration and how the delivery mechanism might be improved for national rollout. The FCE highlights on the other hand, the challenges with uncertain roles and responsibilities leading to rushed implementation and that insufficient technical guidance led to the implementation of a census that was ultimately considered not appropriate. We provide a fuller

mapping and comparison of complementary evaluation activities with the FCE in each country in the 2014 Annual Progress Report.

Broad scope with prioritized in-depth investigation of critical issues

Given the extent of the scope of the FCE on multiple streams in each country, the evaluation team has limited ability to investigate in-depth all aspects of Gavi support. There are indeed limitations with respect to instrument length and the amount of data to be collected for any type of quantitative as well as qualitative data collection. To address this limitation, we have, to the extent possible, limited our primary data collection to those areas for which high-quality secondary data sources are unavailable. From one vantage, this could be viewed as a limitation. From another, it can be seen as an opportunity for the evaluation team to be more selective in focus on exploring with greater depth critical issues that are priority areas for Gavi and for countries.

Prospective approach

Another important contrast compared to previous evaluations of Gavi support, is the prospectively-oriented evaluation approach. A prospective approach enables us to collect information as the implementation process unfolds through participant observation, fact checking interviews, and other methods. This allows us to identify issues in a more timely fashion than retrospective approaches. As key issues arise, these can then be studied in additional depth by incorporating further data collection into KIIs as well as other evaluation components. This includes the opportunity to better adapt different evaluation components in a mixed-method environment such as the aforementioned incorporation of questions identified from the process evaluation in health facility surveys. Furthermore, in Bangladesh a number of issues probed as part of the process evaluation were identified from our observations of campaign sessions. A prospective evaluation approach also addresses a number of other limitations of retrospective data collection as discussed in a later section.

A prospective approach provides an opportunity to inform implementation in a timely manner. In Uganda, our evaluation work identified the absence of guidelines as a factor limiting the use of ISS funds at the district level. Our FCE team communicated this to the national MOH, who responded by providing the appropriate guidelines. These communications are a reflection of the relationships that our FCE teams are developing with EPI programs and partners. Our findings of mid-stream implementation also provide important opportunities for improving implementation in a timely fashion in other countries. For example, the financial sustainability issues around the delivery mode for HPV vaccine in Uganda can be translated into increased scrutiny of financial sustainability issues for other countries considering national HPV vaccine introduction. Our findings around limited capacity to implement multiple support streams may help inform plans for Gavi support implementation in 2015 in Mozambique.

Support stream milestones are, of course, embedded in larger-scale complex systems. The evaluation team recognizes limitations in the current approach to investigate processes beyond the immediate focus of the TOCs. These may include contextual issues in a country that have marked effects on immunization activities (such as political unrest in Bangladesh), and broader initiatives such as general (not stream-specific) provision of technical assistance.

Limited visibility of some elements of Gavi support implementation

While document review and direct observation of meetings and events in country (such as EPI technical meetings and ICC meetings) provide important mechanisms for the FCE to generate timely information,

we acknowledge limitations of the approach with regards to tracking communications and decision-making that occur outside of formal channels. We also do not have visibility into communication that occurs through other more informal channels like e-mail and telephone. In some instances, this has limited our understanding of processes. For example, we do not have a very precise understanding around the decision to shift procurement from the Uganda PPDA system to partners, which is reflected in our robustness ranking for this finding. Also, details of preparations for submission of the IPV applications in Zambia and Mozambique were not explicit in meeting minutes.

Another related limitation of the FCE is that we do not have an equivalent observation mechanism in place at regional and global levels. As the focus of the FCE is on countries, our observation mechanism was developed from a country base, and the resources required to expand this to regional and global levels were beyond the capacity of the FCE. As a result, we do not have the ability to identify issues that arise at these levels in as timely or comprehensive a fashion as we do at the country level.

In the other direction, we also do not have routine observation mechanisms at the subnational level, which limits our ability to identify key issues that are more focal in nature and that are not picked up through our other evaluation components such as health facility surveys.

Reliance on key informant-based approaches may lead to respondent fatigue

As a result of both our limited visibility of some elements of Gavi support implementation as well as a need to investigate key issues in further depth, we rely on KIIs as the primary method for qualitative data collection. These are limited in a number of ways: they are prone to recall bias, there may be reluctance to disclose sensitive or controversial information, and most important given that there are a limited number of stakeholders that are involved across multiple streams and inform multiple components of the FCE, there is significant potential for respondent fatigue. To minimize respondent burden, we integrated multiple topics into single interviews as much as possible. However, as a result of needing to minimize respondent burden, we are not able to study all aspects of Gavi support in equal depth. This emphasizes the importance of the other methods of qualitative data collection, such as observation to minimize the demands on key informants' time. Despite these limitations, the KIIs remain an important mechanism for collecting rich qualitative information that is not obtainable through other data collection methods, and for better understanding findings from process tracking and survey-based evidence.

Data quality and timing of secondary and primary data collection

Relying on secondary data sources in turn means that our evaluation findings are subject to the quality of those secondary data sources. This is most evident in our analysis of HMIS data for examining the rollout. While these data provide a reasonable assessment of the rollout relative to vaccines already in the system, there are notable problems in using these to assess the true level of coverage. For population-based data sources like surveys, we are also reliant on the timing of those surveys and whether they have been conducted in the relevant time period and collected the desired indicators. This is the rationale for the household survey data collection efforts, which focus on biomarker-based data collection. The household survey data collection is currently ongoing and planned for 2015. The limitations with respect to timing of data collection also extend to the FCE's own primary data collection. With the broad scope of the FCE, the health facility and household surveys will only be able to capture the relevant aspects of some Gavi support streams. For example, the survey planned for Mozambique in early 2015 will be ideally timed to measure PCV vaccine coverage, but will be conducted

too early to capture coverage of the rotavirus vaccine introduction in 2015. The FCE surveys will also be limited in their ability to assess progress made as a result of HSS support, as they are not always timed to coincide with the beginning and end of the HSS grants.

Conclusion

In this 2014 report of the Gavi FCE, we extended our evaluation across a broader set of Gavi support streams. These include a focus on cash-based support through the HSS support window in all four countries, the national introduction of rotavirus vaccine in Zambia, the MR campaign in Bangladesh, HPV (demonstration project in Mozambique, preparations for national introduction in Uganda) as well as early findings around the application for IPV. We followed up on the ongoing implementation of PCV in Mozambique, Uganda and Zambia. In addition, we implemented a broader arrange of evaluation components to complement the qualitative process evaluation methods. With the expansion of scope and methods, our findings are notably more diverse than in the 2013 report, which focused on PCV. At the same time, there were a number of common themes that emerge across countries and streams of support. These areas were: Gavi support contributions to new vaccine introductions; limited capacity to implement multiple Gavi support streams; expanded and stronger but still limited partnerships; multiple barriers and slow implementation of HSS; communication challenges between EPI programs, partners and the Gavi Secretariat around Gavi procedures; and a lack of clarity around HPV vaccine demonstration project implementation and the path to national HPV vaccine introduction. Challenges and successes that we identified were then to generate a series of recommendations that we describe in the next section.

Summary of recommendations

Given the diversity of support streams covered in the 2014, we have not develop a set of cross-country recommendations, but provide a summary table of the recommendations developed and based on the key findings in each country report. In developing recommendations, we note that these are based on our evaluation team's view of contextual factors such as political environment, resource availability and institutional operations. Our intention is that Gavi, countries and partners consider these recommendations and further develop steps to operationalize them that are commensurate with their resources and context.

Table 39: Recommendations by country

Finding	Recommendation(s)	Audience	Generalizability
Bangladesh			
<i>Measles-rubella (MR) vaccine</i>			
Bangladesh achieved high awareness of the MR campaign among the population and, subsequently, achieve high coverage of the MR vaccine among the target age group. Differences in coverage were observed, with coverage lower in traditionally lower performing areas, among children with caregivers with no education, and children less than five years of age. High coverage led to large reductions in susceptibility to rubella in the target population. Measles susceptibility was already low prior to the campaign, reflecting historically high sustained routine coverage of measles vaccination and previous measles vaccine campaigns.	<ol style="list-style-type: none"> 1. Following an overall successful MR campaign, the Bangladesh EPI and country-level partners should consider targeted efforts that focus on low coverage areas and groups, as identified by surveillance and coverage data, and shift attention to maintaining high routine MR vaccine coverage. 2. The Bangladesh EPI program and country-level partners should focus future social mobilization and demand generation activities on increasing awareness and understanding of rubella. 	Bangladesh EPI, WHO, and UNICEF	Low. The finding and accompanying are to the MR campaign in Bangladesh.
The MR campaign had a range of positive effects on the routine immunization system, ranging from strengthened delivery systems to increased demand for vaccination. Some negative effects were also noted, including reduced monitoring and supervision of routine EPI due to campaign demands on health worker time. There was also some	<ol style="list-style-type: none"> 1. Gavi and partners should ensure that appropriate technical guidance is provided to EPI programs in the design of campaigns so that positive impacts are maximized and negative impacts are minimized. This includes, but is not limited to, designing campaigns as an opportunity for provision of catch for other vaccines. 	Gavi Secretariat, WHO, and UNICEF	Medium. While the finding is for Bangladesh, ensuring that campaign positive effects are maximized and negative effects are minimized is likely true for other countries undertaking large-scale immunization campaigns. This issue was also highlighted across a number of countries in the March 2015 IRC

Finding	Recommendation(s)	Audience	Generalizability
missed opportunities for catch-up of other vaccines.			report. Clear technical guidance on how countries can achieve this will facilitate this.
The MR campaign was not included under the operational plan (OP) of Maternal, Neonatal, Child and Adolescent Health (MNC&AH) as the plan was developed prior to the opening of the Gavi support window for the MR campaign. In the context of Bangladesh, no money can be allocated or spent for any other activities except the line items described in the endorsed OP. The subsequent lengthy administrative procedures required for the release of funds resulted in a delay in approval of the budget for preparatory activities and launch.	1. Country governments should initiate dialogue internally and with the Gavi Secretariat about country needs and administrative requirements for new support streams well in advance of the opening of the support window to enable timely updating of key operational documents (e.g., Comprehensive Multi-year Plan [cMYP] and).	Country governments and Gavi Secretariat	Low. We propose, however, that this issue is explored more broadly in other settings.
Some campaign delivery points experienced vaccine stock-outs caused by a number of factors. Suboptimal micro-planning and target population registration led to underestimation of the target population which converged with high vaccine demand, resulting from successful planning activities to result in stock-outs.	1. The Ministry of Health and Family Welfare (MOHFW) and country-level partners should draw on MR campaign lessons and continue to invest in maintaining and institutionalizing the strong capacity for contingency management that can be carried forward for future vaccine introductions.	MOHFW, WHO, and UNICEF country offices	Low. This finding is specific to the MR campaign in Bangladesh.

Finding	Recommendation(s)	Audience	Generalizability
	<p>2. The MOHFW and EPI program should explore methods to better incorporate perspectives of stakeholders from various levels of the health system into higher-level decision-making with the goals of strengthening alignment and effectively implementing activities.</p>		
Mozambique			
<i>Human papillomavirus (HPV) vaccine</i>			
<p>The district ultimately chosen as the Gavi-supported site for the HPV vaccine demonstration in Mozambique represents a district with relatively favorable implementation conditions that include strong partner support and comparatively higher socioeconomic conditions. The Government of Mozambique (GOM)'s later decision to include and independently fund two additional HPV vaccine demonstration districts will likely lead to lessons learned which will be more applicable and which will result in tools and plans that are better adapted for national introduction.</p>	<p>1. Gavi and country governments should continue to ensure that selection of demonstration sites maximizes the potential for a representative experience that may contribute to lessons learned for national introduction. This may include supporting multiple demonstration sites in a simultaneous or phased manner and/or encouraging co-financing of additional demonstrations sites by country governments or other donors.</p>	<p>Country governments and Gavi Secretariat</p>	<p>Medium. While site selection was a finding specific to Mozambique, our interviews at the global level suggest that this may be occurring in other countries. A review of site selection in other countries is warranted.</p>

Finding	Recommendation(s)	Audience	Generalizability
<p>Insufficient technical guidance and underutilized technical assistance, coupled with the National Immunization Programme (NIP) and country-level partners' limited knowledge on implementing HPV vaccine demonstration projects led to the unsuccessful implementation of a target population census in the HPV vaccine demonstration sites, which was ultimately abandoned. The resources required to conduct the census resulted in a lack of attention being paid to other preparatory activities that affected the quality of the HPV demonstration project</p>	<ol style="list-style-type: none"> <li data-bbox="730 240 1203 808">1. The Gavi Secretariat and partners should provide technical guidelines for HPV vaccine demonstration project implementation that includes guidance on how demonstration activities relate to national roll out of the HPV vaccine. Relatedly, in guidelines, the demonstrated ability criterion should be revised to more clearly emphasize demonstrated ability based on an average or representative site and conditional on development of a feasible delivery model for national introduction <li data-bbox="730 849 1203 1060">2. Partners and Gavi should ensure that sufficient technical guidance (guidelines, tools, and also technical assistance) specific to HPV vaccine demonstration projects is available and accessible. 	<p>Gavi Secretariat, WHO, and UNICEF</p>	<p>High. As the HPV vaccine involves a target population in other countries that is very different from those for routine EPI, there is likely to be limited technical expertise in country to design delivery models to reach the target population on a routine basis. The absence of specific demonstration project guidelines will affect all countries. A review of technical capacity and assistance needs for HPV vaccine demonstration programs is warranted.</p>
<p>Funds were disbursed early from Gavi, in response to lessons from Mozambique's experience with PCV. The disbursement entity, roles, and responsibilities of the NIP and partners however, changed, from what was stated in the approved application for the HPV vaccine demonstration project support in Mozambique. Even though these</p>	<ol style="list-style-type: none"> <li data-bbox="730 1096 1203 1409">1. The Gavi Secretariat should establish a formalized process for changes to implementation plans that occur after approval, including changes in designated roles and funding recipients. Country governments, country-level partners and the Gavi Secretariat should ensure that changes in 	<p>Gavi Secretariat, country partners, and country governments</p>	<p>Medium. Our finding suggests that the process for changing roles and responsibilities from the initial application are not formalized, which may lead to similar issues in other countries.</p>

Finding	Recommendation(s)	Audience	Generalizability
changes were positive because they better aligned with the purpose of the demonstration project, the changes were poorly communicated across all stakeholders and were not well planned. As a result there was confusion in roles and responsibilities and delayed in-country disbursement of funds to implementing agencies.	<p>these roles are communicated to all relevant parties.</p> <p>2. Gavi should continue to ensure that the leading implementer for demonstration is the MOH if they will be the main implementer for national introduction.</p>		
<i>Health system strengthening (HSS)</i>			
Communication challenges between the NIP and Gavi Secretariat, coupled with competing priorities and staff turnover at NIP and Gavi, led to submission delays in the development of key Gavi HSS conditionalities (Year 1 OP and Monitoring and Evaluation [M&E] framework) and the start-up of HSS support in Mozambique.	<p>1. In countries with limited central capacity and/or other important implementation bottlenecks, country governments, partners, and Gavi should more carefully consider whether implementing multiple support streams is feasible. For Mozambique, this extends to a reassessment of the feasibility of current plans to introduce rotavirus vaccine, measles second dose vaccine, and IPV in 2015 alongside the ongoing implementation of the HPV vaccine demonstration project and the expected start-up of HSS.</p> <p>2. Country governments, partners, and Gavi should consider strengthening central capacity and additional technical support to allow countries to manage and implement multiple support</p>	Gavi Secretariat, Alliance partners, and country governments	Medium. Limited central capacity was a challenge in three of the four Gavi FCE countries is likely to be a problem common to many countries. This is particularly the case in the context of the implementation of multiple streams of Gavi support.

Finding	Recommendation(s)	Audience	Generalizability
	<p>streams. This could be implemented through the existing HSS support stream.</p> <p>3. Gavi should improve communication by jointly developing explicit communication norms, roles and expectations of NIP/MOH managers, key Alliance partners (e.g. UNICEF, WHO), and the Gavi Secretariat, through written and mutually agreed upon terms of references. This should include alternate designees to limit the problem of staff turnover.</p>		
Uganda			
<i>Human papillomavirus (HPV) vaccine</i>			
<p>Key steps in the application process failed to account for the feasibility, sustainability, and ongoing financial resources required for the chosen and tested HPV vaccine delivery model (a combination of school-based and campaign-based delivery) for national introduction. These failures include lack of participation in the application development process on the part of key partners who could have provided this financial perspective, and failure of the Independent Review Committee (IRC) review process to ensure that this</p>	<p>1. Acknowledging that HPV vaccine targets a different age group than other routine vaccines, country governments, partners, and Gavi should more comprehensively consider the costs and plan for sustainability of the chosen national delivery strategy. As this is a specific criterion of Gavi's previous and new application guidelines, it is essential that this be included in the application materials and could be ensured by incorporating a section in the</p>	<p>Country governments and Gavi Secretariat</p>	<p>Medium. Part of this finding stems from the need for a more careful review of financial sustainability by the IRC and Gavi Secretariat, suggesting that this may be occurring in other settings. We suggest follow-up investigation on the issue of financial sustainability of national HPV vaccine introduction in other countries.</p>

Finding	Recommendation(s)	Audience	Generalizability
<p>information was provided prior to approval of the application. This led to a switch to a delivery model based on routine EPI that was not one of the primary models tested as part of the HPV vaccine demonstration project in Uganda.</p>	<p>application template dedicated to the costing and planning for ongoing vaccine delivery. This information should be carefully reviewed by the IRC and Gavi Secretariat.</p> <ol style="list-style-type: none"> <li data-bbox="722 493 1213 699">2. MOHs, partners, and Gavi should increase efforts to integrate the Ministry of Finance into all immunization-related partnerships and the Ministry of Education for HPV-specific partnerships. <li data-bbox="722 743 1213 1162">3. Country governments and partners when designing HPV vaccine demonstration projects should, where feasible, consider including different delivery models that vary in the resources required to implement them. For example, demonstration projects could test whether a lower-cost option of integrating HPV vaccination as part of the routine EPI delivery system is effective. 		

Finding	Recommendation(s)	Audience	Generalizability
Lessons learned from the introduction of PCV led to the Uganda National Expanded Programme on Immunisation (UNEPI) and partners initiating the preparatory phase for the national HPV vaccine introduction earlier than past vaccine introductions. However, there was uncertainty among in-country stakeholders as to when the Vaccine Introduction Grant (VIG) funds would arrive in country to cover the costs of the preparatory activities. This is the result of a mismatch in the understanding of the procedures and timeline for the disbursement of the HPV vaccine introduction grant between the Gavi Secretariat, UNEPI, and partners.	1. The Gavi Secretariat should establish a formal process for requesting vaccine introduction grants which should include details on the timing of disbursement.	Gavi Secretariat	High. This finding is similar to what was reported as part of the 2013 Gavi FCE report and reflects the need for a more formalized process for requesting vaccine introduction grants.
<i>Health system strengthening (HSS) and immunization services support (ISS)</i>			

Finding	Recommendation(s)	Audience	Generalizability
<p>Challenges with the integrated financial management system (IFMS), poor communication between national and subnational levels, non-integration of ISS into the district planning cycle, and a lack of guidelines for districts on how to spend and account for ISS funds have led to slow utilization of ISS funds in Uganda. Notably, the Ministry of Health (MOH) has addressed these challenges; they sent advance communication to districts to notify them of future ISS disbursements and provided guidelines detailing how these funds were to be utilized and accounted for.</p>	<ol style="list-style-type: none"> 1. The Uganda MOH should ensure adequate and timely communication to subnational levels about Gavi cash support so that funds are integrated into the district planning process. The MOH should ensure that Gavi cash support is disbursed to the subnational level with accompanying guidelines on use and accountability. 2. The application and planning process for HSS (and other new vaccine introductions dependent on HSS funds) should more realistically take into account the 	Uganda MOH	Low. This finding is specific to Uganda.

Finding	Recommendation(s)	Audience	Generalizability
Both HSS and ISS implementation were delayed by the protracted time period required for procurement of equipment and civil works through the Uganda government system and the subsequent transition of procurement to non-governmental partners. These delays were exacerbated by the concurrent reprogramming of HSS funds. The country did not anticipate the time that the procurement transition would take and did not fully realize the implications it would have on spending all HSS funds within the specified support window.	<p>time required for government systems (e.g., Public Procurement and Disposal of Public Assets [PPDPA], IFMS) and the time needed for reprogramming. Gavi should consider the time required for reprogramming when setting specified support windows.</p> <p>3. Country governments, partners, and the Gavi Secretariat should more carefully consider the implications on country alignment and efficiency of deviations from government-based systems of funding and procurement. Decisions to switch to alternate funding channels should further consider the time required to undertake these transitions.</p>	Country governments, WHO, UNICEF, and Gavi Secretariat	High. Although the findings are specific to Uganda, challenges with procurement as part of HSS grants have been noted in other evaluations of HSS.
Zambia			
<i>Pneumococcal vaccine (PCV), measles second-dose (MSD), and rotavirus vaccine</i>			
Discrepancies between vaccine consumption and official target population figures that are used to determine vaccine supply, remaining cold-chain inadequacies at facilities, and lack of adequate planning and vaccine stock management at the subnational level contributed to stock-outs of both PCV and rotavirus vaccines.	1. In Zambia, substantial long-term investment and multi-sectorial involvement are required to develop more accurate estimates of target populations for measuring vaccine coverage and determining vaccine supply. In the nearer term, the EPI program with appropriate stakeholders, including districts,	Zambia EPI, Central Statistical Office (CSO), WHO, and UNICEF	Medium. This finding is specific to Zambia, however, supply chain issues are a problem affecting several Gavi support countries as highlight in the March 2015 IRC report.

Finding	Recommendation(s)	Audience	Generalizability
	<p>CSO and partners such as WHO and UNICEF should identify solutions to mitigate the effect of inaccurate denominators leading to vaccine stock-outs</p> <p>2. There should be continued investment in cold-chain capacity, maintenance and logistics should be a key focus on health system strengthening activities in Zambia.</p>		
<p>Ongoing limitations of the vaccine surveillance system, including lack of tools and forms at facility levels, inaccurate denominators, insufficient health worker training, and incomplete reporting limit the ability of the EPI program to track the roll out of PCV and rotavirus vaccine in terms of vaccine coverage, adverse events, and other indicators.</p>	<p>1. Data quality is a key focus of the latest HSS support stream. Consistent with this focus and the findings of the evaluation, the upcoming application for HSS in Zambia should include substantial investments to address the issue of data quality, including ensuring availability of forms and tools, as well as training to ensure accurate reporting.</p>	<p>Zambia MOH</p>	<p>Medium. Although this finding is specific to Zambia, data quality for immunization programs is an issue known to affect many other countries, as also highlighted in the latest March 2015 IRC report.</p>

Finding	Recommendation(s)	Audience	Generalizability
Experience gained through the pilot implementation of rotavirus vaccine in Lusaka province and adaptations based on informal lessons learned during the launch of PCV in 2013 contributed to improved preparation, launch, and roll out of the rotavirus compared to previous introductions. A formal PIE and a longer time period between the introductions could have potentially allowed for greater learning and opportunity to address past limitations prior to the rotavirus vaccine introduction.	1. EPI programs, country partners and Gavi should ensure that learning experiences are maximized for new vaccine introductions. Learning from previous introductions should be based on robust post-launch monitoring and evaluation, including PIEs. This should also include sufficient time between introductions to allow corrective actions to be taken. Another option is to explore further the use of phased introductions such as through the use of pilot or demonstration projects that provide opportunities for early identification and resolution of bottlenecks and partnership strengthening.	EPI programs, WHO, UNICEF, and Gavi secretariat	Medium. Although this finding is specific to Zambia, we note other instances, for example Mozambique, where multiple vaccine introductions are scheduled close in time. This may limit the ability to undertake PIEs between introductions and the opportunity to address deficiencies from previous introductions.
<i>Health system strengthening (HSS)</i>			
Coordination challenges stemming from the different partnership structure for HSS compared to new vaccine introductions, limited experience with the new HSS application process, and multiple competing priorities led to a revision of the timeline for the HSS application submission from September 2014 to January 2015.	1. Ministry of Community Development, Mother and Child Health (MCDMCH) should identify a dedicated point person within Department of Planning and Information to coordinate the application of the HSS grant in Zambia.	Zambia MCDMCH	Medium. Although the finding is specific to Zambia, challenges with coordination for HSS have been noted in previous evaluations of HSS.

Annexes

1. Theories of change for relevant funding streams
2. Small area analysis methods
3. Small Area analysis results
4. Inequality analysis methods
5. Bangladesh MR campaign methods
6. Bangladesh MR campaign results
7. DBS Assay methods
8. Mozambique resource tracking
9. Mozambique NIP: PCV-penta ratio maps
10. Uganda resource tracking
11. Uganda Partnership Analysis
12. Zambia HFS methods
13. Zambia HFS results
14. Robustness ranking criteria

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